

HEALTHCARE WORKER SAFETY AND NEEDLESTICK INJURIES

HEARING BEFORE THE SUBCOMMITTEE ON REGULATION, BUSINESS OPPORTUNITIES, AND ENERGY OF THE COMMITTEE ON SMALL BUSINESS HOUSE OF REPRESENTATIVES ONE HUNDRED SECOND CONGRESS SECOND SESSION

WASHINGTON, DC, FEBRUARY 7, 1992

Printed for the use of the Committee on Small Business

Serial No. 102-60



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CONTENTS

Hearing held on February 7, 1992.....	Page 1
---------------------------------------	-----------

WITNESSES

FRIDAY, FEBRUARY 7, 1992

Adkins, Charles E., Director of Health Standards, Occupational Safety and Health Administration, U.S. Department of Labor, and Susan Harwood, Director, Office of Risk Assessment	48
Arrowsmith-Lowe, Thomas, Deputy Director, Office of Health Affairs and AIDS Coordinator, Food and Drug Administration, Public Health Service, Department of Health and Human Services, accompanied by David West, Deputy Director, Office of Device Evaluation, Center for Devices and Radiological Health.....	46
Bell, David M., Chief, HIV Infections Branch, Hospital Infections Program, National Center for Infectious Diseases, Public Health Service, U.S. Department of Health and Human Services, accompanied by Robert J. Mullan, medical officer, HIV Activity, National Institute for Occupational Safety and Health, Centers for Disease Control	44
Chiarello, Linda, registered nurse, New York State Department of Health.....	27
Christensen, Janet, registered nurse.....	7
Gianakos, Arthur, president and CEO, North American Medical Products	30
Jagger, Janine, associate professor of neurosurgery, University of Virginia.....	12
Johnson, William H., CEO, University of New Mexico Hospital, on behalf of American Hospital Association [AHA]	37
Lashof, Joyce, Dean Emerita, University of California at Berkeley, and president, the American Public Health Association.....	24
Moore, Bob, president, Local 1199-E/DC, Service Employees International Union, AFL-CIO, CLC.....	11
Roe, Jean, certified nursing assistant.....	4
Russell, Barbara, chair, American Nurses Association [ANA], Task Force on AIDS	15
Seifert, Kevin, director of marketing, Bioplexus	34
Spruill, Gwyen, medical laundry transport worker	9

APPENDIX

Prepared statements:	
Adkins, Charles E., with attachment	222
Arrowsmith-Lowe, Thomas.....	216
Bell, David M., with attachments	192
Chiarello, Linda.....	166
Christensen, Janet, with attachments.....	83
Gianakos, Arthur	170
Jagger, Janine.....	143
Johnson, William H.	185
Lashof, Joyce	161
Moore, Bob.....	138
Roe, Jean.....	78
Russell, Barbara, with attachments	146
Seifert, Kevin, with attachment.....	174
Spruill, Gwyen, with attachments	121
Response to request of Chairman Wyden for information before hearing: U.S. Department of Health and Human Services.....	374

	Page
Response to request of Chairman Wyden for information before hearing—Continued	
U.S. Department of Labor	369
Response to request of Chairman Wyden for additional information during hearing:	
American Hospital Association	248
Department of Health and Human Services, Food and Drug Administration	280
Department of Health and Human Services, Centers for Disease Control... Recommendations for Preventing Transmission of HIV and Hepatitis B virus to Patients During Exposure-Prone Invasive Procedures.....	300
Guidelines for Prevention of Transmission of HIV and Hepatitis B virus to Health-Care and Public-Safety Workers	303
U.S. Department of Labor	311
University of Virginia Sciences Center, letter to James S. Benson from Janine Jagger, associate professor of neurosurgery	362
Wyden, Hon. Ron:	
Opening statement.....	62
Subcommittee staff memo	65

ADDITIONAL MATERIAL SUBMITTED FOR THE RECORD

Miscellaneous submissions:	
Health Devices, Special Report and Product Review	495
HIV-AIDS Surveillance Report, Table 3., AIDS cases by age group, exposure category, and sex, reported in 1990 and 1991	522
Becton Dickinson, sharps safety system brochure	523
Photograph	528
Sharp-Trap, Inc., Rick Sawaya, M.D., medical disposal device	529
Sterimatic Safety Needle, brochure.....	567
Statements and letters:	
American Association of Nurse Anesthetists	383
American Society of Anesthesiologists.....	405
Baxter, Cheryl L. Moraca, group marketing manager.....	407
Becton Dickinson and Co., Ted Juraschek, director, Government Relations.....	409
Critikon, a Johnson & Johnson company, David R. Murray	417
Engel-Arieli, Susan L. M.D.....	420
Federation of Nurses and Health Professionals, Candice Owley, vice president, American Federation of Teachers, and chair, Health Care Division	439
International Medication Systems, Limited, Randall J. Wall, president and CEO	455
National Phlebotomy Association, Inc., Diane C. Crawford, CEO.....	460
North American Medical Products, Inc.....	466
Pascall Medical Corp., William R. Tarello, VP, operation	468
Ryan Medical, Inc., Henry H. Kuehn, chairman and CEO.....	472
Safe Tech Medical Products, Inc., Re-Trak, Michael Haining.....	475
Sherwood Medical, David A. Low, president.....	485
Sterimatic Medical Systems, Ltd., John S. Parry, managing director.....	488
Sterling Winthrop, Kathleen M. Whyte, vice president.....	492
Tri-State Hospital Supply Corp., Don Propp, new product development	493

HEALTHCARE WORKER SAFETY AND NEEDLESTICK INJURIES

FRIDAY, FEBRUARY 7, 1992

HOUSE OF REPRESENTATIVES,
SUBCOMMITTEE ON REGULATION, BUSINESS
OPPORTUNITIES, AND ENERGY,
COMMITTEE ON SMALL BUSINESS,
Washington, DC.

The subcommittee met, pursuant to notice, at 10:15 a.m., in room 2359-A, Rayburn House Office Building, Hon. Ron Wyden (chairman of the subcommittee) presiding.

Chairman WYDEN. The subcommittee will come to order.

Today, the Subcommittee on Regulation, Business Opportunities, and Energy continues an inquiry begun almost 5 years ago into the U.S. health industry's efforts to control the AIDS-HIV epidemic. Our focus is whether American healthcare workers are adequately protected in the workplace from exposure to the HIV virus and other bloodborne diseases like hepatitis B. After careful examination, we can only conclude that much remains to be done.

More than 5 million healthcare workers are exposed daily to the deadly infectious disease. When the safety of these workers is in question, their patients will continue to doubt the ability of the healthcare delivery system to protect the public health. If you reduce accidental needlestick injuries, you break the first critical chain link in the transmission of infectious disease.

At issue today is the problem of infection control among those who are on the front lines fighting the disease—the doctors, the nurses, the trained technicians, and support workers who staff the hospitals, clinics, physicians' offices, and other parts of our health system.

What we have seen are three pictures. One is of great professional heroism—individuals who take unavoidable risks daily to treat people whose contagion could cause serious illness or death for the healer. The second picture is one of a system in failure. Many healthcare providers are moving at a snail's pace in acquiring and using new, safer technologies that are now readily available to protect healthcare workers from the accidental spread of disease.

The third and most frustrating picture is of a lack of Federal leadership. After 6 years of bureaucratic wrestling to devise a bloodborne disease standard for occupational safety in this very high risk area, the Government next month will implement a safety rule that is full of holes. Specifically, the Chair is concerned that this standard does not go beyond the use of high-strength

gloves and masks in surgery. No standard has been written to demand use of safer needles, connective devices, and IV lines, the source of real disease risk to workers.

The Chair is going to take a minute for the subcommittee to take a look at one of the safer blood collection devices. For the sake of those whose vision is as squinty as mine, there is a blowup of the needle for the committee as well.

Over one billion blood collection devices are used each year in the American hospital system, but the vast majority are not like this one. The difference here is that this needle is safely retracted in a plastic sheath. In effect, if I stick myself several times with this, there is no puncture. The sharp end of this innovative device only emerges when you press down on the end of the tube collector, in effect, using it like a plunger. When you relieve that pressure, the sharp retracts back into the plastic sheath. It is virtually impossible to receive an accidental stick with this kind of medical device.

It is important that the committee understands the cost differential. The cost differential for a needle device like this is only 8 cents, and it is my view that the kind of investment we are talking about for this safer device—only pennies—is a good investment to make when it takes only one stick from a contaminated sharp to cause the HIV virus, hepatitis B, or any one of a number of other bloodborne diseases that can cause serious illness.

The subcommittee has found that there are an estimated 1 million plus accidental needlesticks per year sustained by public health workers from surgeons to laborers in the laundry room. These accidents have resulted in thousands of cases of hepatitis B, a disease which claims the lives of approximately 300 health service workers each year.

In addition, there is solid documentation of the increasing number of AIDS-HIV transmission cases among healthcare workers from these accidental sticks. The Centers for Disease Control has readily admitted to the subcommittee that the number of documented cases probably is far outnumbered by the number of unreported and undocumented instances of transmission.

The cost of these injuries is staggering. Accidents from needles cost the U.S. health system \$750 million a year just to test the workers who report the sticks.

It is not just HIV and hepatitis B that is involved here. Health workers also face measurable risks of contracting from contaminated needles diseases such as Delta hepatitis, syphilis, and even malaria.

The subcommittee has found that by utilizing new technologies, including syringes, IV tubes, and connective devices, up to one-half of the accidental sticks could be prevented each year.

The question we are especially interested in is what is keeping this state-of-the-art, new technology from being fully deployed? The devices are marketed today by several companies. They do have Food and Drug Administration approval. Medical providers who use them report good results.

As we shall hear firsthand from workers today, infections from these accidents have had a devastating impact on many lives.

So, why aren't healthcare providers purchasing these safer devices? The reasons seem to be twofold. First, as I mentioned earlier, the devices are slightly more expensive than older, less safe needles and connective hardware. As one device manufacturer told the subcommittee, virtually every hospital purchasing agent in the country is taking a wait-and-see approach to newer, safer devices.

But this seems short-sighted. The subcommittee has documented both short- and long-term savings for medical providers. Use of safer devices will save money in reducing mandated post-stick testing all by itself. Add in the treatment costs for those who actually come down with infectious diseases as a result of these needles-ticks, and it is very clear that safety pays.

Beyond these cost issues, these new technologies ought to be standard equipment simply because it is right. The Federal agencies charged by Congress with protection of healthcare workers have failed to demand that safer needles become the industry standard. The Occupational Safety and Health bloodborne disease standard, which is targeted at curbing transmission of infectious disease in the workplace, is certainly a beginning, but the standard doesn't go beyond masks, gloves, and other such shields. Safer needles need to be required.

More importantly, serious questions remain as to OSHA's ability to enforce their modest standard. The Chair wants to note that there are only 140 Federal inspectors for more than 6,000 U.S. hospitals. The Centers for Disease Control's statistical tracking of infectious disease is a system that often misses the boat. They can't say with assurance how many healthcare workers are at risk or what kind of accidents they experience.

We are going to hear testimony today from a healthcare worker who contracted the HIV virus from a needlestick injury, but you would not find her from the statistics kept by CDC because CDC has no specific plan that is relative to the numbers of infected healthcare workers and the way in which they were infected.

Critical information in battling the disease remains unknown today. This is not acceptable, and clearly, the CDC needs a tracking system that monitors healthcare workers like our witness with HIV.

The Bush administration has rightfully declared war on AIDS, but it seems, when joining the fight with new technologies, agencies like the Food and Drug Administration are still in their barracks. After initially approving many of the safer devices, the FDA and other Federal agencies have done little to promote their use.

The bottom line is that all of us—caregivers, hospitals, the Government—must do more to break that critical first link in the chain of infectious disease transmission. State-of-the-art protection can significantly reduce the spread of bloodborne disease among healthcare workers, and all Americans would be safer as a result.

[Chairman Wyden's statement may be found in the appendix.]

Chairman WYDEN. We are very pleased to have a distinguished panel of witnesses. On our first panel we have Ms. Jean Roe, a certified nurses assistant, San Francisco, California; Ms. Janet Christensen, R.N., San Francisco General Hospital; Mr. Gwyen Spruill, Local 79, United Care Central Laundry; Mr. Robert Moore, Service Employees International Union; Ms. Barbara Russell, American

Nurses Association; and Dr. Janine Jagger of the University of Virginia School of Medicine.

If all of you would come forward, we are going to swear you in.

I would like to ask the press and all photographers, because of the need for confidentiality for Ms. Jean Roe of San Francisco, to take no pictures of Ms. Roe throughout her appearance today.

If all the rest of you will come forward, we have certain formalities that we have to take care of. For purposes of swearing the witnesses, if you would just raise your right hand where you are seated now, that would be satisfactory.

Do any of you have any objection to being sworn as a witness?
[Witnesses sworn.]

Chairman WYDEN. We welcome all of you. Please be seated.

The subcommittee has always afforded witnesses the right to be represented by counsel. Do any of you desire to be represented by counsel today?

We thank all of you for your patience and cooperation that you have shown. The committee realizes the sensitivity of some of these situations.

Ms. Roe, I read your testimony last night, and my heart goes out to you. I appreciate your being here. We are going to protect your confidentiality.

I want to thank all our other witnesses who come and express my appreciation for your outstanding advocacy. We are going to make your prepared statements a part of the hearing record in their entirety, so if you could take about 5 minutes and address the principal concerns that you have, that would be helpful to us.

Chairman WYDEN. Why don't we begin, with you, Ms. Roe. Welcome.

TESTIMONY OF JEAN ROE, CERTIFIED NURSING ASSISTANT

Ms. ROE. Good morning, Chairman Wyden and members of the committee.

I am honored to be here today to tell you about a hazard that I and other healthcare workers—

Chairman WYDEN. Ms. Roe, we do have a problem with the infernal microphones here. If you could just boom it up a little bit more and speak into it, that would be great.

Ms. ROE. I am honored to be here today to tell you about the hazards that I and other healthcare workers face every day we go to work—the danger of needlestick injuries caused by unprotected, exposed needles.

Regrettably, I cannot face you in person because I must protect my confidentiality, both to preserve my privacy and to protect myself from discrimination.

I use the name Jean Roe. I am a member of SEIU Local 250. I have been a certified nursing assistant since 1969. I work at a major private hospital in San Francisco. I continue to work there today. I am a healthcare worker who is now HIV infected from a needlestick injury. This is a documented occupational transmission.

If my HIV disease progresses, and I acquire full-blown AIDS, only then will the Centers for Disease Control classify me in their

HIV-AIDS surveillance report under the category called "Other/Undetermined."

I am not an other or an undetermined. I am Jean Roe. I am here today to tell you my story. I believe, as do growing numbers of other healthcare workers, that these injuries and sero-conversions can be prevented. Prevention can happen only if there is a resolve by Government to move against healthcare industry's negligence and excuses.

My needlestick injury occurred 2 years ago while I was cleaning up a patient's bedside table. The patient was newly admitted to my unit and was medically unstable. My first priority was my patient's medical status—stabilizing his condition and keeping him alive. That night, I also was responsible for two other patients, one of whom was also medically unstable. I was trying to cope with a very heavy patient case load.

During my shift, an intern drew blood from the newly admitted patient and had to use two needles to get an adequate specimen for a blood gas. She left one of these needles on the bedside table. It was hidden by gauze. As I cleaned up the bedside table, the contaminated needle punctured my finger. I had no idea that a contaminated needle lay hidden from my view. I couldn't anticipate it, and I couldn't stop it.

While I was doing my compassionate, professional best to care for my patients that night, I was exposed to an unprotected needle with enough HIV-contaminated blood to infect me and to change my life forever.

I could not immediately report my injury. Staffing was so poor that there was no one to take my place. I could not leave my floor to report my injury to the emergency room. Instead, I had to call Employee Health Services the next morning. After explaining what had happened to me, I was told to come in at the end of the day.

This delayed response by Employee Health Services was a violation of accepted exposure management protocol because I needed to be seen immediately if I was to choose the use of AZT as a prophylaxis. Furthermore, I was not given adequate counseling.

I am very nervous.

Chairman WYDEN. You are saying it very well, too.

Ms. ROE. I was told that my exposure was high risk, but not to worry, and also not to tell anyone.

I became HIV positive several weeks later. I was called into the occupational medicine office and given the news of my test results in person. This began my difficult struggle to manage my injury and my infection, to keep my income, and to maintain my dignity. I have lived a nightmare ever since.

I have developed side effects from AZT. I was exposed to tuberculosis before I could be transferred out of my unit. I had to take an anti-TB prophylactic medication and developed peripheral neuropathy. This is painful cramps in my legs. I took an antiinflammatory medication to reduce swelling in my elbows caused by an HIV-related arthritis from the time of infection. I then developed a life threatening perforated ulcer and spent 2 weeks in the hospital.

My problems are not confined to just medical ones. The hospital has attempted to discipline me for using sick time. My confidentiality is constantly at risk.

This nightmare does not affect me alone. It includes every healthcare worker who is exposed to unsafe needles. Every needlestick injury is a serious event whether or not it results in infection.

Let me give you a dose of reality about being a healthcare worker. We are told by management to be more careful, to work slower, and to act safely. This is meaningless when you are working 12 to 16 hour shifts, being called in early, carrying double patient loads, and facing a shortage of trained staff. That sums up the prevention program at my facility and at many other hospitals around the country.

The technology was available in 1990 to prevent my needlestick injury. At that time, my hospital did not use safer needle-bearing devices. I am now infected.

Unsafe medical devices must be taken off the market and medical facilities instructed to choose the best available technology on the market. There are many safer devices now that could have prevented needlestick injuries. My hospital, and most other hospitals, have been reluctant to adopt safer needle-bearing devices to protect all healthcare workers. I am convinced that they will not act on their own despite what has happened to me and other healthcare workers across the country. I am not the only healthcare worker to become infected after an occupational exposure at my hospital.

Universal precautions must become something more than just hospital rhetoric. Universal precautions must be expanded beyond the provision of gloves, gowns, masks, and sharps containers to include safer needle-bearing devices. To protect healthcare workers against infection, we must protect them from dangerous instruments.

Congressman Wyden, you and the other members of this subcommittee can play an important role in the campaign to clean up the workplace and to protect workers from unsafe, dangerous needles. Healthcare workers desperately need safer medical devices and regulations that require that they use them.

It is too late for these devices to save my life now, but they will save people's lives who I cherish and feel are precious—people I respect. Everyone needs protection from bloodborne infectious diseases. Please don't wait for the list of others to grow and grow before effective regulatory action is taken.

To borrow a quote from Jane Doe, my friend and a healthcare worker at another hospital in San Francisco who became HIV positive from a needlestick injury in 1987: "We need to be protected from the needles."

In closing, members of the committee, I would like for you to remember these names—they have become very dear to me. They are other healthcare workers—Jane Doe, Pat Doe, Melissa C., Ron L.—all healthcare workers who are now HIV infected after occupational exposure. Their injuries could have been prevented. We must take immediate action. We must prevent further needlestick injuries from destroying other lives.

I want to thank you very much.

[Ms. Roe's statement may be found in the appendix.]

Chairman WYDEN. Ms. Roe, thank you very much for excellent testimony. I am going to have some questions for you when we are done with our panel, but I want you to know that I am not going to

let the powerful words that you have spoken today go unheeded because this is an issue of enormous importance.

What I feel most strongly about is that people like yourself who are healthcare workers are also advocates for your patients. That is your job, to go out and advocate for your patient. But you ought to have a Government that advocates for you. You ought to have a Government that stands up for you and ensures that you have the safest possible working conditions. Clearly, that was not the case in your situation, and we are not going to let this go until it is changed. I really admire your courage in coming here and speaking out as you have.

I am going to have some more involved questions to ask in a bit after we are done with the other witnesses, but I just want you to know that I am really pleased you are here because your presence is what it is going to take to turn this around and stop other people from being injured.

Ms. ROE. Thank you very much.

Chairman WYDEN. Let's go on to our other witnesses.

Ms. Christensen, welcome. You are from San Francisco as well.

Ms. CHRISTENSEN. Can you hear me?

Chairman WYDEN. You might want to lower it a little bit and speak right into it.

TESTIMONY OF JANET CHRISTENSEN, REGISTERED NURSE

Ms. CHRISTENSEN. Good morning. My name is Janet Christensen. I work at a major public hospital in San Francisco and am a member of Local 790. I have been a registered nurse since 1970. I am grateful for this opportunity to share my story with this subcommittee.

On March 29, 1991, I was working in the pre-op holding room. On a normal day, I can start anywhere from 5 to 15 IV's on patients before they enter the operating room. A standard angiocath is stocked.

The morning of the needlestick injury, I was working my way through the cases waiting for the operating room. An anesthesia attending resident and a medical student came to the bedside of a patient while I was starting an IV. I was having difficulty, so the medical student stepped over to assist me. After I got into the vein, he handed me the IV tubing. As I was withdrawing the needle from the sheath in the patient's vein, the medical student's free hand swung back and hit the contaminated stylet on the fleshy, palm side of his hand. The needle penetrated deeply into his hand.

This type of exposure is extremely high risk. It is a large bore needle. It is hollow. It is full of blood, stuck deeply into a highly vascular area, the hand. We also knew that the patient was at high risk to be HIV positive because he had just gotten out of prison and had a history of IV drug abuse. The patient said that he had tested negative in the past. The student and I felt great relief.

We followed hospital protocol for a needlestick injury. We obtained a consent to test the patient's blood, although we had to wait for this consent because the patient had been premedicated with narcotics. The medical student called the hospital post-exposure hotline to start the protocol. He elected to start AZT immedi-

ately because it was a Friday, and the patient's HIV status would not be known until after the weekend.

On Monday, the results came back HIV positive. By that time, the medical student was already having adverse reactions to the AZT. This reaction, coupled with the patient's test results, was a depressing blow for him. I felt extreme empathy and guilt when he told me the results. I was so sorry for what had occurred and kept replaying the incident in my head to see what had gone wrong. The medical student's reaction to the AZT drug became so overwhelming he had to withdraw from his clinical duties.

A month later, a colleague who had worked in the emergency room showed me a self-covering Critikon angiocath. In the emergency room it was standard issue. As I looked at this device, I realized that the medical student's needlestick injury never needed to occur. If I had used this angiocath, the student would have hit the plastic barrier that covers the contaminated needle instead of the needle that penetrated his skin.

I also realized that this needle might well have prevented another needlestick that had happened recently in the same area of the hospital.

I called the administrator of central supply and requested that we be given a stock of safer needles. I was told that the chief of Employee Health Services had decided that the protected/safer needle would only be stocked in the emergency room and ambulance areas. The rationale was that the staff in those areas didn't have access to needle disposal boxes.

I then embarked on an incredible odyssey into the maze of hospital bureaucracy. I filed a grievance with the help of my Union in June 1991, to demand safer needles for the entire hospital, not just selected areas. The grievance was settled in my favor by Mr. Richard Cordova, the hospital administrator, in November 1991. The devices still have not been made available, nor do we have a plan in place to do so, but slowly the newly formed bloodborne infection control committee is working its way toward that goal.

I work in an institution that has been a leader in research relating to HIV infection and post-exposure protocol for workers. The difficulty I had gaining access to safer medical devices and establishing a committee to reduce exposure is probably much worse in healthcare facilities where they feel an AIDS problem doesn't exist.

Universal precautions are not enough to protect healthcare workers from bloodborne disease. We must demand of the industry that they produce high-quality products that truly are safer and that hospitals use these products to protect workers.

Healthcare workers are caring for increasing numbers of HIV-infected people who are entering the system at earlier phases in the disease and with the introduction of new drugs and better treatment are living longer. If healthcare workers cannot feel safe at work, they are less productive and wonder whether the job is worth risking their lives for. If education and safer working conditions can lower the risk, then every effort must be taken to ensure that this occurs.

Thank you.

[Ms. Christensen's statement, with attachments, may be found in the appendix.]

Chairman WYDEN. Miss Christensen, your testimony is very helpful. I will have some questions as well.

Anyone who just listens for a few minutes can see the pain you are feeling as a result of your colleague being in this situation. I want you to know that is the kind of testimony that we need to have. It is very helpful. I will have some questions.

Mr. Spruill, welcome.

TESTIMONY OF GWYEN SPRUILL, MEDICAL LAUNDRY TRANSPORT WORKER

Mr. SPRUILL. Good morning. My name is Gwyen Spruill. I am a steward for Local 79 of the Service Employees International Union. I am grateful for the opportunity to come here today in support of safer medical devices.

I work as a transporter for a laundry facility in Wayne, Michigan, just outside of Detroit. This laundry facility provides full laundry services to eight Detroit area hospitals. My job is to transport soiled linen from the hospitals and unload it at the laundry for sorting and cleaning.

You might think that because we work in a laundry, with no direct patient contact, that we are not at risk for contracting diseases like hepatitis B or HIV. The truth is laundry workers, housekeepers, food service workers, and other so-called downstream workers are often exposed to used needles, scalpels, and other surgical instruments that are contaminated with blood.

Let me tell you what it is like working in a hospital laundry. It is not unusual to pull up to a dozen needles, lancets, and scalpels out of the laundry every month.

I would like to show you some of my findings.

What I have shown you here is the real deal. These are not needles that are clean. These are contaminated needles. The needles that are in front of me now, they could be contaminated with HIV or hepatitis B or all kinds of infectious diseases. We have whole used IV systems with dangling needles showing up in the laundry.

Once, the entire surgical tray, over 150 used and bloody instruments, came through wrapped up in the linen. We were averaging at least a half dozen reported needlesticks per year. Both myself and the other stewards have received needlestick injuries. They only tested us for hepatitis B, and we both were negative.

This is what would happen when one of us got stuck with a sharp. The worker would be sent to the clinic and given a few shots. I guess they were for tetanus and hepatitis B, but most of the time they didn't even bother to tell you what they were treating you for.

Then the worker would be handed a bag of condoms and told to use them for the next 6 months. There was no medical followup. I can't even put into words how stressful this kind of treatment has been for many of my coworkers. At that time, there was no follow-up training or support. There was no plan for ensuring it would not happen again.

Several years ago, I and another Union steward, Sue Hickman, began dealing with the problem of needles and other sharps coming

through mixed in with the laundry. It has been a long, hard fight, and it is not over yet.

I first approached management in 1989 for some kind of protection against all the needlesticks that coworkers were getting. When management failed to respond or come up with a plan, I began saving all the sharps that came through the laundry for documentation and filed a complaint with my OSHA. Within just 2 weeks, we collected over 200 needles, scalpels, scissors, and other sharps from the soiled laundry.

I have a photo. What this photo shows is the type of things that come through a laundry.

The display I have in front of you, these are objects you can see with the naked eye. But those objects that are shown on the picture are hidden objects because they come in half a bag or a plastic bag, so an employee has no way of knowing that when he digs his hand down into the linen that one of those sharps could stick through his hand or leg or whatever part of the body.

The photos were taken by Michigan OSHA during their initial inspection in February 1990. Michigan OSHA cited the hospital that was the source of most of the sharps we collected. After the first inspection, the number of sharps coming through dropped off for a few weeks. But now, 2 years later, the hospital is still appealing the citation, and we are still getting stuck with needles. I brought here today what we have pulled out of the laundry just in the last few weeks.

I think it is great that OSHA released the bloodborne disease standard this past December and that universal precautions are now the law. Because of our Union's grievance procedure and our own efforts to get the law enforced, we now have been trained on universal precautions. We get hepatitis B vaccine free of charge. We even have latex gloves. But the bottom line is that needles and sharps just keep coming.

Although most needlestick injuries occur at the point of disposal and for downstream workers, engineering controls like self-sheathing needles give us the best and sometimes the only protection.

The latex gloves we have offer no protection against needles. What we really need are safer medical devices.

Thank you.

[Mr. Spruill's statement, with attachments, may be found in the appendix.]

Chairman WYDEN. Mr. Spruill, thank you. Your testimony, as well, is very helpful to the subcommittee. I will have some questions in a minute.

I think what you say is so important. It is fine to talk about healthcare issues in a congressional hearing room while Members of Congress look at various kinds of reports, documents, and sheets, but you have taken it into the real world—the hospital laundry room—where someone like yourself, dips down into those towels or dips down into the materials. You shouldn't be exposed to these kinds of risks that you are talking about.

Let me also tell you that I am not sure Chairman Dingell is your Congressman in Wayne, but I know he is certainly close by, and he is the chairman of the committee that has jurisdiction over the various health agencies. I am also going to tell him of your story

and your concerns because he has had a long-standing interest to improve worker safety and will want to work together on it.

I thank you. We will have some questions in a moment.

Mr. Moore, welcome.

**TESTIMONY OF BOB MOORE, PRESIDENT, LOCAL 1199-E/DC,
SERVICE EMPLOYEES INTERNATIONAL UNION, AFL-CIO, CLC**

Mr. MOORE. Thank you. My name is Bob Moore. I am president of district 1199-E/DC of the Service Employees International Union.

On behalf of our 400,000 healthcare workers who are members of SEIU, I would like to thank Chairman Wyden and the other members of the subcommittee for this opportunity to testify on safer medical devices.

My written testimony has been submitted to the subcommittee in advance, and I ask that it be included in the record.

Chairman WYDEN. Without objection, so ordered, and, Mr. Moore, we are very grateful to you for that. I think that it is almost a biological compulsion for all of us to read our statements to each other, and I know we may be here until dinner time if we don't move along, so I appreciate that. We will put your entire statement into the record.

Mr. MOORE. I thank you.

I would like to make some major points here.

You have heard testimony from my brothers and sisters here who are healthcare workers and who are on the front lines of the AIDS epidemic in this country. They know firsthand the hazards of HIV, hepatitis B, and other bloodborne diseases. They also know the inadequacy of the protection that their employers provide.

There is an epidemic of needlestick injuries in this country, upward of 1 million every year. Management says these injuries are the fault of workers who should accept them as part of their job. When workers express concern about the risks of infection, they are told to slow down and be more careful.

I am mindful of a member of our Union a couple of years ago who was infected with hepatitis B. As a result of reporting it, he was consequently fired after 10 years of service to his employers because they decided he was a risk to the patients.

Some hospitals threaten workers with disciplinary action if they suffer too many needlesticks. This advice is absurd. It is dangerous, especially where there are shortages of trained staff. That is most likely the norm, as our members are often short staffed.

SEIU encourages local unions to meet with management to initiate needlestick injury prevention programs, and broad worker participation is essential for an effective program of injury reduction.

Strong Government action is also needed. A crucial step is improving reporting and surveillance of needlestick injuries. They should be reported in OSHA 200 laws and reported to the Food and Drug Administration.

At the same time, we need better reporting and surveillance by the Centers for Disease Control of occupationally acquired cases of HIV infection as well as fully developed AIDS.

CDC should make occupational risk a separate reporting category and stop hiding them under "other/undetermined." We can't prevent these infections without better information on how they occur.

Next, CDC should update its 1987 recommendations on universal precautions to address the need by using safer needle-bearing medical devices.

CDC should recommend changes in medical practices and procedures inherently unsafe. Universal precautions alone won't prevent needlesticks. Safer technology already exists and is available in the market. Several manufacturers have taken the lead. But much more needs to be done.

SEIU petitioned FDA in April 1991, to develop performance safety standards for medical devices that contain needles. FDA action is needed because the new OSHA standards require employers to control exposure with engineering controls that is safer medical technology and equipment. We think FDA has an important role to play here.

SEIU applauds OSHA for issuing a final standard on exposure to bloodborne disease—but the delay is inexcusable. We have known about the risks of hepatitis B, the hepatitis B virus, since the late 1970's. We first requested this standard in 1986.

OSHA should set up a special emphasis program to make sure the standard is strongly enforced. Clear compliance guidelines on engineering controls are needed.

I have it written here, but it is upsetting to know the American Dental Association, American Health Care Association, and Home Health Services Association, organizations you would expect to put their patients first and sworn to do that, actually have challenged the new OSHA standards in court. I think it is important to note that these groups, I think, are behaving in a very irresponsible way, and if their real concern is for patients, they would make sure workers as well were not contaminated or hurt.

We are confident the courts will reject their pleas. Healthcare workers like you have heard from today will care for them when they need them without hesitation or discrimination. The question they are asking is who will care for them, the healthcare worker. Thank you.

Chairman WYDEN. Mr. Moore, thank you. We will have some questions for you in a moment, and thank you for the cooperation your organization has shown the subcommittee throughout.

[Mr. Moore's statement may be found in the appendix.]

Chairman WYDEN. Ms. Jagger, let's go to you next.

TESTIMONY OF JANINE JAGGER, ASSOCIATE PROFESSOR OF NEUROSURGERY, UNIVERSITY OF VIRGINIA

Dr. JAGGER. My name is Janine Jagger. I am an epidemiologist and researcher at the University of Virginia. I have been studying needlestick injuries since 1985, focusing on the product design hazards and how product design can be modified to protect healthcare workers who have to handle the devices.

Congressman Wyden and committee members, I appreciate the opportunity to testify before this committee today and to shed light

on an issue that has remained in the shadows far too long. I believe that the seriousness of the needlestick problem in the healthcare setting has been underestimated and that healthcare workers, as a risk group for HIV, have been grossly neglected.

I bring a message of both despair and hope. Despair because the lives of tens of thousands of healthcare workers each year are unnecessarily devastated by occupational exposure to HIV and other pathogens, and the toll continues to mount, unabated. I am hopeful because we now have technology to reduce the most frequent and serious of occupational blood exposures, needlesticks, to a small fraction of today's levels.

Unfortunately, few healthcare workers have had the chance to benefit from these advances. I wish to stress the urgent need to employ all possible means to bring safer technology into the hands of healthcare workers as quickly as possible.

The number of healthcare workers affected by needlesticks is staggering. Current estimates are that about 1 million needlesticks occur in U.S. healthcare settings each year. Of those, 2 percent, or about 20,000 needlesticks, are likely to be contaminated by the AIDS virus, HIV. If available surveillance data are correct, we would then expect between 50 and 80 healthcare workers to become infected by HIV each year.

We are all aware of the tragic consequences to those who are infected by HIV. However, the consequences to those who sustain HIV-contaminated needlesticks, even when infection does not occur, can also be devastating.

As many as 20,000 healthcare workers each year must endure months of uncertainty while waiting to learn if they have contracted HIV. The exposed individuals, many of whom are in their child-bearing years, are compelled to take the same precautions as infected individuals until transmission can be ruled out. Many suffer devastating effects on their personal lives, even though they have not contracted HIV.

Some take an experimental course of AZT in hopes of reducing the probability of HIV infection. Although there is no indication in practice that AZT is effective for this purpose, there is a high likelihood of short-term side effects and an unknown likelihood of long-term side effects.

The research that my colleagues and I conducted at the University of Virginia has challenged the conventional and, I would add, incorrect, view that needlesticks are caused by the carelessness of healthcare workers. Our studies provide evidence that unsafe product design causes most needlesticks and that relatively simple design changes can prevent them.

For example, we were astonished to learn that about 50 percent of needlesticks were caused by unnecessary needles, that is, needles used to access intravenous equipment and not used to pierce the skin. This was not unique to our hospital. The use of such unnecessary needles is common practice, even today.

Furthermore, an array of needleless and shielded needle alternatives are available right now that could eliminate 50 percent of needlesticks tomorrow if hospitals were adequately informed and motivated.

For the remaining devices that require needles to pierce the skin, such as blooddrawing devices, intravenous catheters, and syringes, it is possible to provide a fixed barrier between the hands and the needle after use, that allows the hands to remain behind the needle as it is covered. Examples include a sliding sleeve feature that pushes forward after use and locks beyond the length of the needle or a feature that allows the needle to be retracted backward after use into a rigid housing. Devices meeting these criteria are also available today.

Our data tells us that the elimination of unnecessary needles and the replacement of conventional unsafe needles with protective designs could result in a 90-percent reduction in needlesticks from hollow-bore needles. Theoretically, this level of prevention could be achieved now.

What are the barriers that keep this technology out of the hands of healthcare workers?

The voices who speak out for safer medical devices for the protection of healthcare workers have been few and, they have been weak. The relevant Government agencies—including the FDA, the CDC and OSHA—have been passive on this issue, although medical device safety, infection control, and occupational safety fall squarely into their respective domains. The three agencies have demonstrated a recognition of this issue by sponsoring a joint conference on this topic, chaired by Dr. Murray Cohen of the CDC, and scheduled for next August.

However, much more is needed. Policy commitment, program development, and research support are lacking.

Another barrier occurs at the hospital level where those making purchasing decisions are often administrators who are least likely to be informed about the benefits of safer products. Cost is sometimes cited as a barrier to purchasing new needle designs.

However, I do not believe that safety will cost more in the long run. As safer devices begin to dominate in the marketplace, competition and economy of scale will bring the prices down. There are already examples of safer devices that cost less than their hazardous counterparts.

The higher price of a safer device must also be weighed against the savings from reduced needlestick rates. The cost of a needlestick that does not result in disease transmission can vary from \$200 to \$1,000.

The response of industry to the need for improved technology has been varied. Among the major medical device manufacturers, some have pursued the development of safer devices—for example, Baxter, Critikon, and Becton-Dickinson. Others have categorically ignored the safety concerns raised by their products—for example, Terumo, Sterling, and Wyeth.

One troubling practice may obstruct the development of safer needles. Some companies acquire exclusive rights to key patents with the sole intent of preventing other companies from developing competing products. I am aware of such an instance in the field of safety needles, and I believe that, when the technology has the potential to save lives, this practice should be illegal.

Finally, a major barrier to the acceptance of these new and safer devices is a lack of reliable documentation of their performance in

hospitals. When the efficacy of needlestick-preventing technology has been adequately demonstrated and communicated, it will become increasingly difficult to justify the purchase of conventional needles.

Support for this important research has not been available through Federal funding channels. This remains a critical need.

The protection of healthcare workers from the hazard of needles-ticks has been tragically neglected. Federal agencies, product manufacturers, and front line healthcare workers must work together to get safer devices into the hands that need them. This transition cannot happen fast enough. Today alone, February 7, 2,400 healthcare workers will have sustained preventable needlesticks, and 50 of them will plunge needlessly into crisis and uncertainty as they begin their wait for HIV test results.

Let us pursue every possible avenue to increase the availability of needlestick-preventing technology. Let us put a halt to the needless tragedy in our healthcare workplace. Thank you.

[Dr. Jagger's statement may be found in the appendix.]

Chairman WYDEN. Doctor, thank you for a very informative and very helpful presentation. I have known about your excellent research for some time.

Chairman WYDEN. Ms. Russell, welcome. We will make your prepared statements a part of the hearing record as well. If you could summarize your principal concerns this morning, that would be very helpful also. Welcome.

TESTIMONY OF BARBARA RUSSELL, CHAIR, AMERICAN NURSES ASSOCIATION [ANA], TASK FORCE ON AIDS

Ms. RUSSELL. Thank you.

Good morning. I am Barbara Russell, chair of the American Nurses Association's, ANA, Task Force on AIDS. I have been a practicing nurse for over 30 years and have specialized in the prevention and control of infections for the last 18 years. I appreciate the opportunity to testify today representing ANA.

I am also representing the American Association of Critical-Care Nurses, AACN, the Association of Operating Room Nurses, AORN, the Association of Nurses in AIDS Care, ANAC, and the Emergency Nurses Association, ENA. We commend the committee for holding hearings on safe medical devices and needlestick injuries to healthcare workers, an issue of critical concern to nurses.

America's 2 million nurses constitute the largest number of healthcare workers in the industry, practicing nursing and providing healthcare in many settings. We are patient advocates who, since the early days of the HIV-AIDS epidemic, have been at the forefront of movements to provide comprehensive, compassionate care to those with AIDS and HIV infection. AIDS patients require almost double the amount of nursing time required by equally ill patients.

We believe reducing the risk of transmission of bloodborne diseases in healthcare settings for the protection of patients and healthcare workers is of paramount concern. Nursing has advocated education and training regarding the use of universal precautions and infection control for our profession and the public.

Nurses are keenly aware of the hazards of exposure to HIV and to hepatitis B which may result from contact with patients' blood or body fluids in a number of settings. Blood and body fluids are the field in which many nurses are immersed as they work. Although personal protective equipment is worn as needed and reduces the hazards of infection, the risk of exposure to bloodborne pathogens may still exist.

The greatest risk of transmission of infectious agents to health-care workers results from sharps which puncture the workers' skin.

Despite knowing the data shows a 0.4 percent chance of infection with HIV following a needlestick or cut with a sharp object, nurses are human and have fears like anyone else. The greatest fear of a nurse who has sustained a needlestick is that it will ultimately result in a potentially life threatening illness.

For nurses who have contact with the blood or body fluids of HIV or hepatitis B-infected patients, the months following the occupational exposure may be a nightmare. These nurses must be counseled, their risk of infection evaluated, and their fears addressed. They must take steps to protect themselves and their families. It means adhering to safer sex practices and delaying family planning decisions. Something as simple as a fever must be assessed as a symptom of HIV or hepatitis B, HBV. Postexposure prevention medical treatment must be considered.

Further, these nurses must be tested repeatedly for months, and each test result awaited with great anxiety and strain to the nurses and their loved ones. The emotional toll can be very great.

A California nurse tells her harrowing account of being stuck by a needle while caring for an AIDS patient. The nurse tells a story of fear, anxiety, and nightmares. A single mother, she spends the late night hours calculating how old her son will be if she gets sick. She continues to be tested for HIV.

The article appended to our testimony is a painful testament to the emotional impact of needlesticks. We ask that it be included in the record of this hearing.

Chairman WYDEN. Without objection, we will make those articles a part of the record.

Ms. RUSSELL. I have stories of other nurses, but I think you have been told of those experiences from other nurses here.

The Centers for Disease Control have documented at least 40 cases of HIV seroconversions among healthcare workers; 17 are nurses; 36 were the result of sharps injuries.

Needlestick injuries are a fact of life in the profession of nursing. It is an unfortunate hazard of the profession. However, in the face of the AIDS epidemic and the prevalence of hepatitis B, needlesticks have become far more anxiety inducing.

We urge immediate and ongoing research, development, and evaluation of devices and equipment intended to reduce the risk of injury from sharps and of personal protective equipment designed to reduce exposure. In order to reduce the risk of exposure to bloodborne pathogens, we support the consistent and strict use of universal precautions, the availability of proven safety measures, the standardization of methods to ensure equipment is safe, and the

continued evaluation and modification of work practices to ensure optimum safety in the workplace.

Containers for disposal of used sharps must be conveniently located. The use of protective medical devices based on research data and scientifically sound, effective practices, where feasible, must be mandated.

Data indicates that the largest group of exposures to blood involve needlesticks—500,000 to 1 million a year—a significant number of which could be prevented by the use of engineering controls such as easily used protective sheaths for needles.

However, we recognize that such devices may not be appropriate for all needles. The cost of the safer medical devices must not be so prohibitive as to have an adverse impact on patient care or staffing. Therefore, continuous education and training as urged by the CDC and OSHA to ensure safe handling of such equipment must be provided. Although needle and sharp disposal containers are widely available for use, not all hospitals provide them in convenient locations.

Enforcement of, and compliance with, the OSHA bloodborne standard is an effective response to the risk of HIV transmission in healthcare facilities.

We recognize the need for continued research and data collection on HIV transmission in the healthcare setting in order to increase the body of knowledge on which policy decisions are made.

Accurate reporting of adverse incidents involving exposure to bloodborne diseases can only be accomplished in an environment that acknowledges and has a full understanding of the critical nature of such information. Several agencies, including CDC, OSHA, and FDA, receive or require reporting of information. We support the reporting of adverse outcomes of exposures to these agencies.

Although we acknowledge the need for all these reports, we must reiterate our concerns about confidentiality of person-specific information and data.

Our organizations continue to work with CDC and OSHA to ensure development of effective policies and resolutions which encompasses education and prevention regarding bloodborne pathogens. Additionally, we urge Congress and the Federal and State agencies such as FDA, CDC, OSHA, and EPA to work together. The agencies must have appropriate funding to ensure timely regulatory actions, adequate qualified staff, resources, commitment, and leadership in ensuring enforcement and compliance of relevant existing regulations. Certainly, agency action is also critical for product effectiveness, safety, and cost evaluation.

As healthcare professionals, we understand that HIV transmission is reduced by strict adherence to universal precautions and other infection control practices, as well as by intensive education of consumers and healthcare professionals. Student health professionals who are not covered by OSHA regulations must also be educated about disease and equipment management and use. OSHA has documented historically that inexperienced workers have more adverse occupational incidents.

Education of all healthcare workers about use of an enforcement of universal precautions in the workplace is critical to reducing the risk of transmission and must be ongoing.

We have undertaken educational programs on HIV disease and AIDS in the workplace setting and the OSHA standards for employee protection both nationally and with our individual State and regional bodies. We have pushed for better compliance and enforcement of CDC and OSHA standards. We support Federal policies which would require annual education for all healthcare professionals to ensure that they are current on universal precautions.

We strongly believe that these efforts must be coupled with engineering controls—the most effective line of defense for worker protection against sharps injuries.

Mr. Chairman, we support immediate systematic research and evaluation studies of devices and equipment intended to reduce risk of injury from sharps, and of personal protective equipment designed to reduce exposure risks, funding to support systematic studies, availability of proven safety devices, continued evaluation and modification of work practices to reduce the frequency of situations where exposure and/or injury risk to healthcare workers is greatest, and ongoing development and refinement of new safety devices.

We thank the committee for the opportunity to testify today and look forward to working with you on the development of sound public policy to protect healthcare workers and healthcare consumers.

Thank you.

[Ms. Russell's statement, with attachment, may be found in the appendix.]

Chairman WYDEN. Ms. Russell, thank you for your very helpful presentation.

You said that the student professionals weren't covered. How many people are we talking about with that omission?

Ms. RUSSELL. Thousands. Maybe I could get some help here, but there are student nurses and student lab people. They are not considered employees.

Chairman WYDEN. Physicians as well?

Ms. RUSSELL. Student physicians; yes.

Chairman WYDEN. It is very helpful. I have always enjoyed working with your organization. Ms. O'Neill in Oregon is one of the leaders in the nursing field. I appreciate your excellent testimony.

Let me begin with you, Ms. Roe. The testimony you have given was so strikingly similar to me. Similar in this respect: It is the kind of thing that could happen thousands and thousands of times a day at a hospital, a clinic, a physician's office, and home health program. Virtually any of these programs, it seems to me.

As I understand it, you had a heavy work load that particular evening. You were trying to juggle your heavy work load. An intern gave you some help. An intern draws blood from a patient who is seriously ill, and unstable, as you described it. What happened, essentially, there was something that covered up the needles—gauze. It could have been, almost anything—a filmy light kind of material.

Isn't that the kind of thing that can happen thousands and thousands of times a day in healthcare settings across this country? It isn't something that is a rare and aberrational kind of situation.

Ms. ROE. Yes; that is correct. It is happening nationwide.

Chairman WYDEN. Ms. Christensen.

Ms. CHRISTENSEN. Yes.

Chairman WYDEN. Get your microphone. The one thing I want to make sure we nail down is that the kind of thing you two have described is not some kind of anomaly or rare occurrence but the kind of thing that can potentially happen anywhere and many times a day. Is that right, Ms. Christensen?

Ms. CHRISTENSEN. Yes; it can happen even if the needle is in full sight. You are working under conditions that are less than optimal. You are moving quickly to try to save somebody's life or get something done or save money or save time, and you are not thinking about that.

Chairman WYDEN. Ms. Roe, if you would, take us through what seems to be a bureaucratic, never-never land that you face as a healthcare worker once you have been injured. We have these charts and have been looking at the various kinds of programs, but it almost seems like kind of a bureaucratic water torture that the healthcare worker faces.

Could you elaborate a bit on that point?

Ms. ROE. I haven't seen the chart, but I can tell you that I called my employee health center at 8:30 in the morning. There was no answer. I called back at 9, and I wasn't given an appointment until 4 o'clock in the afternoon.

That is just not adequate at all. I should have been told to come in immediately. Then, when I got there, I was told not to tell anybody. I did not receive counseling. I was told to practice safe sex practices. All of these barrage of things I was told then. It was high risk but not to take it serious and not to worry about it too much.

Chairman WYDEN. If Government doesn't move to deal with these kinds of issues, is it your sense that some of the people in this country, particularly young people who care about human needs and who want to serve in the healthcare field, are going to say that this is a profession that can't protect them and look into other fields?

Ms. ROE. I believe that the reason that needlesticks are underreported by the CDC and OSHA is they want to keep nurses coming. They want to keep interns coming. So, it is not in their best interest to say that needlesticks are occurring, that HIV and hepatitis B are occurring in the healthcare setting.

Chairman WYDEN. Ms. Christensen you have been a nurse for more than 20 years and have been on the front lines. What is your sense about what will happen if these kind of occupational exposure risks aren't reduced? Will you have trouble getting young people to go into the field?

Ms. CHRISTENSEN. When I became a nurse 20 years ago, I didn't know I would have to sacrifice my life to take care of patients. If I knew what I know today and was determining what field that I wanted to participate in, it would not be healthcare.

Chairman WYDEN. Mr. Spruill.

Mr. SPRUILL. My feeling about the situation is that the biggest concern to employers is money. The bottom line. Employees can be replaced because there are millions and billions of people who need jobs. At the end of the year, if they have spent money to protect their employees, it is a payday for him, extra money in his pockets.

Chairman WYDEN. From the standpoint of training, Ms. Roe, do you think that the training has been adequate regarding the handling of these needles and sharps?

Ms. ROE. No; I don't believe so.

Chairman WYDEN. Is there any significant training program at all?

Ms. ROE. There is a video that our hospital shows employees, but it is my understanding that all employees don't see this video. Housekeepers don't see it, and yet, housekeepers get needlesticks every day at my facility.

Chairman WYDEN. So, we've got people who get no training at all.

Ms. Russell just mentioned you could have thousands of people who are exempt from the rules altogether including student health-care professionals. In your situation you felt that people were simply reluctant to come forward because of bureaucracy, red tape, and fear of ostracism. It doesn't sound like there is much of a system out there today. That is what we want to turn around. I really admire your coming and speaking out. That is why it is so important to have you.

Just one other question for you, Ms. Christensen, and you, Mr. Spruill. I think you may have touched on it. Is it your sense that the OSHA standard, because it leaves out sharps and needles, is still missing a significant component of what needs to be done to protect workers?

Ms. CHRISTENSEN. The CAL/OSHA standards don't go far enough. It is my estimation they have to be incredibly explicit to get hospitals to participate. It is my observation the hospitals, when given a choice between choosing a safer device, a less safe device, and a nonsafe device, will look at the bottom line in terms of how much it costs. Repeatedly, they have taken the low bid on disposal boxes that don't work as well as other disposal boxes that are more expensive. I think the hospital industry will continue to do this as they are squeezed financially.

Chairman WYDEN. Mr. Spruill, on that point.

Mr. SPRUILL. As a laundry worker, I feel we are on the hidden end, that the most important thing is giving us safer medical devices.

Chairman WYDEN. You mentioned, Mr. Spruill, that when you brought the dangerous practices to their attention that you were just given condoms. Is that essentially the entire program that you were part of in terms of trying to deal with these health and safety risks?

Mr. SPRUILL. Yes; that was part of it.

But my first experience was when I brought it to management's attention—to their attention—it was a joke. I would bring the needles up, and my fellow employees would report to me, and management would throw them away, throw them in the trash can.

The reason I knew they were throwing them in the trash can was a simple fact. One day I just happened to take a look, and the needles were in the trash can. That is when I filed my OSHA report.

When my OSHA inspector came out, the managers and I sat down and had a little conference with him. He asked the department head where are the needles that this employee gave you. He said I don't have them. I threw them away. That was when I took it upon myself to, for every needle I gave management, keep four myself. From that point on, we had them all through the laundry and our manager thought that he had thrown all the needles away. I poured out and covered a table about half the size of this with all types and with blood in them, wheelchair parts, dentures, pace-makers, along with needles, scalpels, and other things I mentioned today in my testimony.

Chairman WYDEN. What you have described seems very insensitive to the workers. It seems that what you faced was the hospital just throwing the materials away. The sharps and needles would expose other people to the disease, like garbage people and sanitation folks. Is that your sense? Not only were they not serious in responding to you, but their response was to essentially produce additional risks and exposure for other citizens.

Mr. SPRUILL. We are not considered important. Our work is not considered anything at all. We are not considered like the doctors and nurses. Not that I have anything against nurses and doctors, because I feel we all should be protected from these types of diseases, but we are considered nobodies.

Chairman WYDEN. Let me just ask one question of you, Mr. Moore. Do you think that there would be any problems in getting CDC to change its recording and reporting systems and still protect worker confidentiality? It would seem to me that you could do both. That was a concern of Ms. Russell as well. Do you see any problem, that would cause your workers problems with confidentiality, in getting CDC to put in place these new reporting systems?

Mr. MOORE. Well, of course you can come up with a system that would provide for reporting and provide for confidentiality if everyone puts their mind to it. I understand there is at least one hospital in San Francisco which has a system in effect where people report, and they are given a code number, and their name is protected. Only one person has the code numbers used from that point on.

Chairman WYDEN. That is helpful, because, as I looked at it, and Ms. Russell raised the point again, I think all would want to be sensitive to protecting the confidentiality of workers. But whether it is code numbers or something else, it seems to me we could still get these reporting systems in place and protect the rights of workers.

I appreciate your answer, and I know that has been important to your organization as well.

Ms. Jagger, just a couple of questions for you. We are going to have the medical providers on the next panel. What would be your message to them be if they raise concern about costs or the kinds of issues that you brought up today? What is your message to those providers?

Dr. JAGGER. When you say medical providers?

Chairman WYDEN. The Hospital Association will be up. We may have others, but they will be medical providers, and those who, when faced with the good research that you have done, might talk about cost or might raise other concerns. What would be the message you would want to give to providers and management who would have to pay for these safety devices?

Dr. JAGGER. I think my main message would be that I do not think that safety will cost more in the long run. We are looking at first-generation technology right now, and I am very much aware of second-generation technology that is in the pipeline, which is more elegant, more streamlined, fewer parts than what we see now. In other words, we can design even more efficient devices, and this will be an ongoing product development. It is not going to stop with the devices you see on the market now. As these devices become more accepted the volume in production will go up, competition will come into play, and prices will come down.

I think that hospitals play a very important role in promoting this technology so that prices can come down. We must get over this initial cost barrier in order to get the benefits of this technology also at a reasonable cost.

The situation that we are in today is we are producing these devices in low volume. Soon, when they become more widespread, the prices will come down, and I believe that we will save money on safety by preventing costly needlesticks.

Chairman WYDEN. Would it be fair to say this country can't afford not to promote these new technologies and can't afford not to move now so as to generate both the savings and the opportunity for better healthcare down the road?

Dr. JAGGER. Yes; I agree with that statement. I think it is really imperative to promote the introduction of this technology as quickly as possible.

Chairman WYDEN. Are there needles being used, Dr. Jagger, in your view that ought to be banned?

Dr. JAGGER. I mentioned during my testimony that there is a very high proportion of unnecessary needles in use. We have currently many, many alternatives for this technology now. In fact, we always have needleless technology to substitute for hypodermic needles used on IV lines. We have had stop-cocks and Luer-Loks for decades. In Europe they never used unnecessary hypodermic needles in conjunction with IV lines.

This is a practice—an inappropriate practice, an inappropriate adaptation of existing equipment in the United States. Because we have had needleless equipment available and because there is a new generation of additional devices to prevent using these unnecessary needles, I see no reason why that practice cannot be immediately stopped and made mandatory.

Chairman WYDEN. You mentioned several companies that you felt were sort of dawdling in terms of moving to bring more innovative products on line. Are they producing some of these needles that ought to be banned or restricted?

Dr. JAGGER. Yes; the hypodermic needles. They are kind of a generic needle that can go on an IV line or go on a syringe. The hypodermic needle is being produced by Terumo, and the other two

companies, Sterling and Wyeth, produce prefilled cartridge syringes, and about half of those syringes are used to give injections into IV lines. They are used for IV line flushes. About half of the needles on those prefilled syringes fall into the category of unnecessary needles.

Chairman WYDEN. The only other question I have for you, Dr. Jagger, and you, Ms. Russell is if you would outline for me what kind of research at this point would be most helpful. Given the fact that you all have cited, and I believe correctly so, the need for additional Federal research in this area, since funding funds are going to be tight, what Federal research according to you, Doctor, and you, Ms. Russell, would be most helpful at this point in getting us new technologies that are cost-effective?

Dr. JAGGER. First of all, I think that the most useful and helpful kind of data collection should begin in the hospital itself. Every hospital in this country can collect needlestick data at the point of reporting needlesticks that contain standardized medical device definitions. If data were collected in this manner across the board, we would be conducting automatic product evaluations as new devices are introduced into these hospitals. That is something that can be accomplished relatively easily. It is not a very invasive system for a hospital to employ.

We need to have information on the devices causing the sharp object injuries and the needlesticks right from the point of use. Such standardized methods can be widely disseminated so that we can get very rapid feedback and comparable feedback from a variety of hospitals. Information can be merged in a compatible format if everyone is collecting data using the same definitions.

I think that kind of very widespread effort would help to promote safer technology much faster, because one hospital may take months or more than a year to test one new safety device. But if data can be merged from a variety of hospitals, we can get that information much faster.

Chairman WYDEN. Ms. Russell, on the point of Federal research and what would be most helpful.

Ms. RUSSELL. I certainly concur with Dr. Jagger. Many of us do collect that data. It would be nice for it to go to a central place. I almost wonder if CDC could establish a program—they have NIS, which is a system of collecting hospital-acquired infections.

Chairman WYDEN. Sounds too logical.

Ms. RUSSELL. Many of us have the data which Dr. Jagger refers to. We do use it within our own institution, speaking for my own place of employment, as to what we can do. Do we need to change procedures? Can we buy a piece of equipment, whatever it might be?

The other thing I would tell industry is many of us are willing to help them try their products out. I myself have been involved in a lot of evaluations. However, you still have to buy the product. Yet, we are providing a product for them. Many of these products, when you put them into use—the first generation—don't work in use all the time. We need to collect that data so we know what to tell the companies to go back and improve for second and third generation. Many of us would be willing to do that, which would be very helpful.

Chairman WYDEN. I have to tell all of you that I would probably ask you questions for another hour or two. You all have been extremely helpful. We very much appreciate Ms. Roe, in particular. You worked under very difficult circumstances.

Let me remind the folks in the press, both those who want to shoot pictures for the newspapers and electronic media, that there cannot be any pictures of Ms. Roe.

Thank you very much. Thank you.

Chairman WYDEN. We are going to take a 5-minute recess.

[Recess.]

Chairman WYDEN. The subcommittee will come to order.

We appreciate the cooperation of our witnesses during the 5-minute recess we had. We had so many devices and materials that I think we needed a little extra time. We thank you all very much for your patience.

I think most of you are aware that it is the practice of this subcommittee to swear all the witnesses who come before this subcommittee. Do any of you have any objection?

[Witnesses sworn.]

Chairman WYDEN. Let me also remind all our witnesses that you have a right to be represented by counsel throughout your appearance here today. Do any of you desire to be represented by counsel?

Chairman WYDEN. Let us begin then with Dr. Lashof of the American Public Health Association. We have enjoyed working with you, Doctor. I want to get you that microphone if we could. We do have microphones here. Maybe lower it a little bit and speak right into it. Welcome.

Let me also say to our witnesses that I am going to make your prepared remarks part of the hearing record in their entirety. If you could take 5 minutes or so to summarize the principal concerns in your prepared remarks, it will be really helpful and, most importantly, will make sure you all can get out before dinner time and get a bit of your weekend as well.

Doctor, please.

TESTIMONY OF JOYCE LASHOF, DEAN EMERITA, UNIVERSITY OF CALIFORNIA AT BERKELEY, AND PRESIDENT, THE AMERICAN PUBLIC HEALTH ASSOCIATION

Dr. LASHOF. Thank you very much, Congressman. It is a pleasure for me to be able to appear before the committee. We do appreciate the opportunity to work with this committee as we have over time.

I am president of the American Public Health Association. Our Association is a professional society that was founded in 1872, representing all disciplines and specialties of public health. As the world's oldest and largest multidisciplinary society of public health professionals and community health leaders, APHA has, throughout its 119 year history, been in the forefront of countless efforts to protect and promote personal and public health.

Since the outset of the human immunodeficiency virus, HIV epidemic, in the United States, the Association has led efforts to secure adequate resources and to assure that the formulation of policies and programs to deal with the epidemic are based upon scientific principles and sound public health practice.

Healthcare workers are at risk of acquiring hepatitis B virus, HIV, and other bloodborne infections through needlestick injuries and other occupational injuries which result in significant exposure to bodily fluids. The CDC estimates between 6,000 and 8,000 healthcare workers are infected with hepatitis B each year, resulting in 200 to 300 deaths annually. Nearly all of these are preventable through a program of vaccination of healthcare workers advocated by APHA and now incorporated in OSHA regulations. There is a vaccine for hepatitis B, but, unfortunately, there is not one for HIV.

Exposure to HIV is of particular concern to healthcare workers because of the high mortality rate and lack of curative treatment at this time. Recent studies have shown that the risk of acquiring HIV infection is approximately 0.4 percent following exposure through the skin to HIV-infected blood. This is almost 100-fold less than the risk of hepatitis B infection after comparable exposure, but HIV is about 100 times as lethal.

There are no Federal monitoring systems currently in place to track the extent of potential occupational exposures to bloodborne pathogens such as surveillance of needlestick injuries. Universal precaution guidelines were recommended by the Centers for Disease Control in 1987. They recommend that all hospitals adopt an infection control policy by treating all bloodborne fluids as potentially infectious.

However, CDC efforts to monitor occupational exposure to blood are limited. AIDS cases which cannot be classified into any of the standard AIDS risk categories are tracked and evaluated by CDC, but there isn't a separate occupational transmission category. There is a registry of persons known to have been occupationally exposed to HIV. However, there is no systematic monitoring of healthcare worker injuries involving blood or surveillance of different types of medical devices to assess the degree of work protection.

There is a general consensus that the number of healthcare workers infected with HIV through occupational exposures is greater than officially reported, although AIDS case reports suggest that there is no epidemic of illness through occupational injuries comparable to that of hepatitis B in healthcare workers.

We believe an important step would be the initiation by CDC of a formalized surveillance system of occupational injuries of healthcare workers in which exposure might occur.

The Occupational Safety and Health Administration is currently in charge of enforcement of existing regulations concerning universal precaution guidelines but does not track the extent of occupational exposures to HIV.

The OSHA Occupational Exposure to Bloodborne Pathogens standard requires employers to implement procedures that include: Use of gloves, masks, and other protective barriers to reduce exposure, care in the use and disposal of needles and other sharp instruments, training and appropriate disinfection, and sterilization of instruments and other reusable medical equipment.

Employers also must develop written infection control plans to eliminate or minimize employee exposure. OSHA enforcement of this standard will include onsite inspections and the imposition of civil and criminal penalties for violators. APHA looks forward to

the implementation of this standard and to its strong enforcement by OSHA.

The Food and Drug Administration reviews medical devices and decides whether to give them FDA approval for marketing in the United States but does not track the incidence of needlestick injuries or other occupational exposures to bloodborne pathogens. FDA plays an important role in preventing transmission of bloodborne pathogens in the occupational setting.

In 1990, FDA promulgated regulations to improve the quality and reliability of medical gloves, but the design of needle-bearing devices has not been addressed by FDA thus far. Because the OSHA bloodborne pathogen standard does not define criteria for medical devices, employers are left to make their own interpretation of the performance safety criteria for needle-bearing devices.

Because APHA does not have the means to reach healthcare workers in the medical setting, we defer to medical groups on the issue of educational efforts to individual healthcare workers about needlestick injuries. However, through our annual meeting and policy participation at the national level, we do engage in our own efforts to increase awareness about this issue.

For example, at our 1991 annual meeting in Atlanta, seven sessions dealt with this subject. APHA has a policy entitled Occupational Transmission of Human Immunodeficiency Virus that urges healthcare employers to educate employees about bloodborne disease and also urges employers to provide the necessary equipment for workers to protect themselves from exposure.

In closing, because of the risks to healthcare workers of acquiring HIV and hepatitis B through needlestick and other occupational injuries, APHA supports strict adherence by employers to the OSHA bloodborne pathogens standard. We also recommend that CDC implement a surveillance system to track the extent of occupational exposures to bloodborne pathogens. It is also important that medical devices and equipment are evaluated to assess the degree of worker protection provided and that proven safety devices are made available to healthcare workers.

Finally, APHA believes that performance safety standards for medical, that is, safer needle-bearing devices, need to be set.

Thank you.

Chairman WYDEN. Doctor, thank you.

[Dr. Lashof's statement may be found in the appendix.]

Chairman WYDEN. I will have some questions in a moment. But I am very pleased that you have gone through some of the issues relating to these numbers and what the numbers and statistics mean in this area, that CDC has acknowledged to the committee that the number of documented cases of HIV virus transmission as a result of accidental needlesticks is nowhere near as great as the number of undocumented cases as a result of people being fearful of coming forward.

It seems to me that our challenge here is to engage in basic prevention. If you are going to break that first link—that very first link—in the chain of transmitting infectious disease, this is the place to make the investments in prevention. I appreciate you putting those numbers in perspective, because I think the principal challenge here is not to have just a debate over the number of

cases that have been documented thus far, versus the number of cases that have been unreported, but to put in place a real strategy so you maximize your investment in prevention, so we aren't involved in playing this catch-up game of trying to reduce the risk further down the line say in the laundry room or somewhere else.

Let's go next to Ms. Chiarello.

Ms. Chiarello, we welcome you. You have worked with us on a number of inquiries. Please proceed.

TESTIMONY OF LINDA CHIARELLO, REGISTERED NURSE, NEW YORK STATE DEPARTMENT OF HEALTH

Ms. CHIARELLO. Thank you, Congressman Wyden and members of the subcommittee. I really appreciate this opportunity to share New York State's perspective on this important issue. My name is Linda Chiarello, and I am a certified infection control practitioner with the New York State Department of Health, AIDS Institute.

First, let me share the magnitude of the sharps-related injury problem in New York State and the risk for bloodborne disease transmission. We are the epicenter of the AIDS epidemic, with over 42,000 cases of AIDS reported through 1991. One quarter of a million of our citizens are believed to be infected with HIV.

During 1991, over 27,000 patients were hospitalized in New York State with an HIV- or AIDS-related diagnosis. In New York City on any one day, around 1,100 patients with HIV or AIDS are being cared for, and in some cases this can represent 20 percent of a hospital's census. Occupational injuries and disease exposures are not uncommon, but the extent of the problem is not precisely known.

HIV infection is not reportable in New York State. There is no system to track occupational exposures to bloodborne pathogens. Hepatitis B infection is reportable, but there is little information that is available specifically about healthcare workers.

During 1990, New York State surveyed all hospitals and requested information on the reported incidence of sharps-related injuries and disease transmission, and 80 percent of the hospitals responded. They indicated that between 1986 and 1989 over 40,000 sharps-related injuries were reported by New York State healthcare workers to their employee health services. These resulted in 23 recognized cases of hepatitis B transmission and 3 cases of HIV seroconversion.

We believe this figure underestimates the true degree of risk for two primary reasons. Hospitals in and around New York City, where the intensity of patient care and the concentration of HIV are highest, were less likely to respond to this survey.

In addition, the literature has shown that 40 to 60 percent, sometimes higher, of sharps-reported injuries go unreported. Additional evidence of risk has been provided in a 10-hospital pilot study of devices designed to prevent needlestick injury.

Incidence data for 1990 and 1991 in 6 of the 10 hospitals revealed 2,064 reported sharps-related injuries and 28 of those were known exposures to hepatitis B, 156 or 7.6 percent of the exposures were to HIV, and these data may change as the additional hospitals are added to this database.

This gives you, then, some picture of the magnitude of the problem in New York State and underscores the urgency to address the issue of sharps-related injuries. Until recently, prevention efforts in New York mirrored those of other States and Federal agencies; namely, issuing guidance documents on universal precautions and preventative strategies encouraging hepatitis B vaccination, but there is relatively little oversight to determine the compliance with these directives.

In 1990, at the urging of New York State Unions, legislation was enacted which permitted the establishment of 10 pilot studies to determine the practicality and effectiveness of devices designed to prevent sharps-related injuries.

Four areas of needle use were targeted for interventions because of their frequency of association with needlestick injuries. These were intravenous delivery, intravenous catheter insertion, injection equipment, and phlebotomy equipment, and 14 different devices were evaluated. Most related to the delivery of intravenous medications.

We are in the process now of analyzing that data. However, it is evident from preliminary analysis that the implementation of safer equipment has had a positive impact, particularly on injuries related to IV delivery systems.

In five hospitals that implemented safer IV delivery systems hospital-wide, either just before or as part of the pilot study, there was an average decline of 25 percent in overall sharps-related injuries in that 1 year.

In three hospitals that implemented the systems during 1991, sharps-related injuries in the second half of the year dropped an average of 41 percent, and IV-related injuries dropped an average of 82 percent. This impact cannot be ignored.

With other study devices, study designs precluded an institution-wide impact analysis. However, with few exceptions, no injuries resulted from the use of the safer technology, and it appears, at least in one hospital, that safer injection equipment decreased injuries related to that aspect of care by 30.4 percent.

This is exciting, and it is encouraging data which speaks to the potential impact of a safer technology, and gives direction for immediate priorities. However, this must be tempered with the economic reality. The incremental cost of these devices varied significantly.

In our study, hospitals applied for incremental cost reimbursements which ranged from a low of 3.4 percent to a high of 1,800 percent. The mean incremental cost, excluding the one device in the extreme range, was 2 times the cost of devices being replaced or augmented. For IV delivery systems, these costs ranged from 2½ to 6½ times what they were currently spending.

While a decrease in injuries will offset these costs, these savings are not always visibly apparent to hospital administrators. There are other market barriers that also impede implementation of a safer technology, including withdrawal of products once introduced, and delays in acquiring or maintaining adequate volume due to production problems.

There are factors which influence user acceptability, and these must also be recognized and addressed. Devices which require

major changes in technique or the need for additional steps will be implemented less frequently. Devices which require that the safety mechanism be activated by the user will also impact on the acceptability and effectiveness of the device, and I can share with you two anecdotal experiences that were shared by the hospitals.

In one case, the hospital looked at the contents of a sharps container that had used needles in it. These were decontaminated and then opened, and they found that 50 percent of the injection equipment was not being disposed of properly; the safety sleeve was not being pushed forward, indicating that the mechanism was not being activated. In one other case, a physician who did not understand how to activate the safety mechanism turned and struck an employee, causing a needlestick injury.

These are the challenges that can and must be addressed. To do so, however, requires a coordinated national effort that involves Government agencies, the healthcare industry, Unions representing workers, manufacturers, inventors, and workers themselves.

It is clear from our experience that devices with integrated safety features—the preferred option—must be evaluated clinically.

Those involved with the New York State project believe there is a need for a central clearinghouse to establish design criteria for each type of product and to weed out those products that have no place in the armamentarium of devices to provide healthcare, and there are many. We believe this will require the FDA to assume a more prominent role in establishing standards for these products.

There is also a need for economic incentives to both encourage research and development of a safer technology and to encourage its introduction into the healthcare setting. Finally, I would like to acknowledge the efforts of so many in the manufacturing industry who are indeed committed to developing and promoting a safer technology. We need their support, and they need ours. I believe together we can make healthcare a safer environment in which to work. Thank you.

[Ms. Chiarello's statement may be found in the appendix.]

Chairman WYDEN. Thank you very much, Ms. Chiarello, for an excellent presentation. I think what you and your colleague, Dr. Lashof, have both done is give us a very good overview of exactly what this challenge is all about. We have heard on the first panel, Mr. Spruill, who works in the laundry room.

He brought what seemed to be an awful lot of contaminated products, a lot of sharps, needles that had been collected in that laundry room over a fairly short period of time. We take that information plus the helpful information that you all have given us about many instances that are undocumented and about some of the price considerations.

I think we are going to hear in a bit that, to the extent that we get more products out, we generate more competition, which lowers the prices further and addresses some of the concerns that you rightfully addressed, Mrs. Chiarello, about the manufacturing, and then we will be on our way to a comprehensive program.

I will have some questions for you in a moment.

Chairman WYDEN. Mr. Gianakos. Welcome, and we appreciate your patience.

**TESTIMONY OF ARTHUR GIANAKOS, PRESIDENT AND CEO,
NORTH AMERICAN MEDICAL PRODUCTS**

Mr. GIANAKOS. Thank you. My name is Arthur Gianakos, and I am the president and CEO of North American Medical Products. I would like to take this time to thank the chairman of the subcommittee for inviting me to attend this hearing on this very critical issue.

North American Medical Products was established in 1984 and introduced one of the first products to address cross-contamination in the anesthesia environment with a disposable, fiber-optic laryngoscope, which is used to help anesthesia and anesthesia nurses or nurse anesthetists look into the airway to carry oxygen into a patient, either prior to surgery or during respiratory failure.

Traditionally, stainless steel equipment is used, and a lack of proper cleaning techniques accompany them, and in many cases, just rinsing a laryngoscope with plain water was the norm.

Over the last few years, the cleaning procedures have improved, but due to the cost and lack of manpower, many hospitals still do not sterilize these products. Habits have been hard to break, and so, we, as a company, continue to face resistance to these systems which were designed to remove the concern of cross-contamination.

Over the years, North American Medical Products has added new products to its line with the intent of providing quality, practical, and economical products to the healthcare industry. In September 1990, we developed a needle protection device called the Safe-Site, which offers the hospitals a universal system which is used to protect healthcare workers in approximately 70 to 75 percent of the needle injection requirements, thus, a comprehensive system which will make training easier and effective.

Additionally, we have developed the Safe-Site to eventually house the remaining 25 to 35 percent of the hospital needlestick requirements, but this will take money. As a small business pushing to grow larger, we fall into the proverbial cash-flow crunch.

We have committed ourselves to addressing this issue because we believe that the everyday danger of accidental needlestick must be addressed, not only for the immediate safety of the hospital and physician office staffs, but for the future of our young men and women who today think twice about committing into the medical profession due to the chance of contacting the HIV or HBV virus. Hospitals around the country, in fact, are facing the difficult task of trying to retain their present employees as well as attracting new ones.

With the Federal monitoring systems in place to determine the extent of accidental needlesticks, I believe they are adequately in place. OSHA bloodborne disease standards address many of the concerns relating to healthcare protection. However, in the very near future these new standards must be made to allow for the benefit of new protective devices.

An example being, when a needle is covered by a protective device, and recapping is now made possible, and there is no risk for a worker to contact any part of his skin on to the needle, then OSHA must establish this fact and provide standards to hospitals to allow recapping with this type of protective device.

I have a product of ours which I would like to show to the committee which is one we have developed. This is the Safe-Site system. It is a very simple system, easy to push forward. The nurse will push it forward from the back end, pushing the sheath over the needle after injection.

This is a system, one little system here that can cover the IV's for piggybacking secondary medication sets. It could be used to attach a syringe to the back end of this here, any size syringe, including prefilled syringes, and it was designed so that it makes it very easy for the nursing staff, even in the IV purview when doing their piggybacks to use the same system during the course of their piggyback and just simply hang it with the set as they are using it over a period of 24 to 72 hours.

With the extender we have added to it, they can now reintroduce a new needle each time, thus saving the hospital significant money on a very simple device. This is just some of the technology that is available and other things that we are working on.

Chairman WYDEN. Mr. Gianakos, I need to interrupt. I think it would be relevant to ask right there what is the price differential between that product and the more traditional product?

Mr. GIANAKOS. Well, to further go into that, there is probably no more than a dime to 15, 20 cents, depending on the nature of where they are going to use it.

If they are using it in IV's over a period of 72 hours and just replace the needles, the cost is insignificant. When they go into 10 cc's or better with our syringes, it is only a dime difference between what they are currently using with syringes and needles. But there is more beyond that. There is also the savings associated with treatments and so forth which I would like to get into.

Currently, as a medical manufacturer, I have also been involved with the FDA regulatory review process on medical devices and particularly with regard to sterile products. I have found these audits thorough and professional and their examiners to be fair and understanding, particularly to small businesses like ourselves.

However, they require the same compliance from us as any other company and request our compliance to their recommendations within reasonable timeframes. I will state, however, that one of the things that we found, as a device manufacturer for needle protection products, is that, up until this past December, the restrictions, or the lack of restrictions, by the FDA on products coming out in the market were not as they are in place now. They have become more stringent.

It used to be you could get a premarket notification of 510(k) within 60 to 90 days. Today, they have extended that to almost 150 days or longer because of their concern of the number of products that have entered into the marketplace, so we have seen some crackdown. Whether it is positive or negative, is unclear. There is still more effort being placed on the products that are being developed and asking us for more documentation and so forth.

Federal policies and procedures, specifically new OSHA standards, will be a factor in forcing some hospitals to comply with the purchasing of needle protection devices and other sharps medical devices. However, Federal agencies must ask insurance companies

to carry some of the burden of forcing hospitals to move into this direction.

It has come to my attention through one insurance company that accidental needlestick injuries have surpassed back injuries in claims made to workmen's compensation. No doubt the AIDS scare has much to do with more nurses reporting these sticks. The insurance dollars that many hospitals could save on their premiums could easily surpass the cost of the medical devices. The reduction in cost of initially healing these healthcare workers and the follow-up treatment would generate even greater savings.

Insurance companies must offer these incentive savings to the hospitals to move faster on these issues. May I note on that, it is estimated that premium savings of up to 10 to 15 percent per hospital could be realized. That would transcend into approximately \$200,000 a year in savings to a hospital. That is just in insurance premiums.

The cost of treating patients would average somewhere in the neighborhood of another \$84,000, or \$85,000. Some of the medical devices like our own would probably cost the hospital no more than \$75,000 to \$80,000 in total and reduce the premium costs as well as the treatment costs associated with the needlestick injuries.

North American Medical Products originally was involved with anesthesia and anesthesia nurses who explained their concerns to me at various trade shows and what would be needed in the marketplace. As a result of these discussions, I proceeded to design and develop the Safe-Site which would allow for a universal protector as opposed to a single niche system. This would make training easier and reduce inventory costs to the hospitals as well. We have accomplished this goal and have received positive feedback both in the United States and abroad.

The problem that we currently face with hospitals not moving quickly is cost or perceived cost. Many purchasing or administrative departments do not realize that, in the course of a year, the hospital will realize monetary savings as well as the positive influence on the psyche of their employees.

There have been a growing number of devices for various niches which have entered the marketplace, and many hospitals are trying to weed through the types to choose the one they prefer. This has caused confusion and even delay in many cases of finalizing decisions. These delays relate to cost, evaluations, review committees, and the period of time to finally go and do something.

With regard to medical staff attitudes toward these new devices, there are many who feel an absolute need for these products, and there are others who will tell you that they do not have a problem in their departments. Some healthcare workers have little difficulty in breaking old habits. Their concern for protection has caused many to accept and adjust to the new technology.

I want to add something to that. One of the things we face as a manufacturer, and I have seen this out in the field, is that many of the healthcare workers will tell you, well, this is difficult to use, it is an awkward system, or something like that, which fortunately we don't face on multiple situations, but they do come up.

It is the short-sightedness of trying to adjust to these systems, especially now, as Ms. Chiarello has mentioned, as the technology in-

creases and gets better, we will get through those problems, but for now we have some technologically advanced products available that may have some adjustment periods involved in them, and we hope that the medical staffs will be patient enough to adjust to these type of systems.

I feel that this trend will continue to grow and new personnel will be trained properly on new systems that will become the standard.

Finally, the plight of the small business manufacturer must be addressed, particularly in this industry where new and exciting products are developed to help mankind.

I have previously highlighted on this topic which addresses the financial aid needed to assist companies like ourselves, not in the form of loans which we already have, and which usually are not enough, and ultimately squeeze the company entrepreneur personally.

What the Federal Government must do is provide Federal grants for companies like ourselves who have invested in the design and development of these products and to use these funds for high production equipment, working capital for inventories, marketing expenses, and additional R&D for even more advanced and cost-effective products. The benefit of high-volume production equipment helps reduce hospital cost and allows companies like ourselves to meet the demands which will be needed in the age of protection.

May I add on that, too, I have a suggestion, if I may make that, Mr. Chairman. I believe that the Federal Government should form a committee to establish a grant program for companies, not for high technology, for computers and so forth because ultimately if nothing has been done to address this issue, you may not have enough people to man those computers.

The problem is that we need the funds that could be allocated like a college scholarship program, based on the needs of the company, the size of the company, and its financial condition.

The same program could work with small businesses to encourage their innovative technology and to help encourage these businesses to grow. That is where we are falling behind here and abroad. The Japanese and other countries do provide programs that are readily available for the funding of these type of programs, and I suggest very strongly that the committee could take this into consideration and present it to the full Congress at some point down the road.

[Mr. Gianakos' statement may be found in the appendix.]

Chairman WYDEN. Very helpful, Mr. Gianakos. I certainly think the Government trying to promote these new technologies and investing in new technologies is an awful lot better investment than a lot of these tax cut gimmicks and programs that are running around Washington. I appreciate your comments in that regard.

Let me make sure I heard you correctly, and maybe I just missed it. Did you say that there was insurance data available that would indicate that there are a larger number of injuries as a result of accidental needlesticks than there are back injuries of healthcare workers?

Mr. GIANAKOS. That is correct.

Chairman WYDEN. What insurance company has that data?

Mr. GIANAKOS. The insurance company I deal with is an insurance agency that represents St. Paul's Fire and Marine Insurance. They are particularly involved in the Workmen's Compensation Programs, and this is where they told us about this latest data, and I have that in writing as well.

Chairman WYDEN. We would very much like that submitted as part of your testimony. We are going to follow that up. That certainly ought to wake up anybody with respect to this very severe issue. If St. Paul or another major insurer has evidence indicating that there are a larger number of injuries to healthcare workers through accidental needlesticks than there are with back injuries, that ought to mobilize just about anybody to get serious about the problem.

We are going to follow up on that data, and your presentation was an excellent one. We will have some questions in a moment.

Mr. Seifert, welcome. Your company is Bioplexus. We will make your prepared statement part of the record. We still have another panel to go.

TESTIMONY OF KEVIN SEIFERT, DIRECTOR OF MARKETING, BIOPLEXUS

Mr. SEIFERT. I appreciate it. I will move right into the highlights. I would like to thank you, not only for the opportunity, but more for the fact that we are all here today. I think this is the first step in a positive direction that has been needed to be made for quite sometime.

We have heard many of the facts associated with hepatitis and HIV, the exposure for the healthcare workers, and that this is well long overdue, and I thank you for that.

To cut into the chase a little bit here, one of the things being involved with the company—I should say my name is Kevin Seifert. I am the director of Marketing with a new company, Bioplexus out of Tolland, Connecticut.

We are in a situation where we are going into the hospitals and trying to implement these products. It is very interesting that the general response to the infection control nurses and the nurses and the healthcare workers as a group is cost justification, and I find that quite amusing in a sense that, if I was to sit here today and to tell you that there is a group of fast food restaurants that has a disease that is being exposed through fryolators from orders of French fries to between 2 to 300 people, and it was costing just a dime to eliminate that per order of French fries, I don't think we would have that discussion.

We are now talking about healthcare workers who are in a position to take care of each and every one of us at some point over the course of our lives, yet we are not advancing the tools into their hands that they deserve. No one is going into a sawmill and talking about a person who is not wearing safety goggles because the cost of safety goggles versus the loss of an eye is apparent. Here we are talking about lives, not sight.

I would like to address something that is an ongoing business situation for the safer medical device industry. As mentioned earlier,

we are coming out of a phase of first generation into second generation.

I think that there has been a great deal of success in removing needles and in-line systems. Those are slowly becoming more cost-effective, but we are in a scenario where, whenever we need to take a fluid from a patient or give an injection when an IV is not administered, there does need to be some type of penetration into the skin. In that case, at this point in time with technology, we are left with using a needle, and we do need to address that.

There are many types of devices that do require manipulation, and just as when the first car came out, we would not be using that today if it had never advanced, and these devices are advancing.

I would like to show you what we believe is the second generation that is occurring, and you were kind enough to mention in your opening statements. This is a phlebotomy needle, and once it is done being used for drawing bloods, once taken from the patient, it can be accidentally stuck or bumped into someone's hand or, if it is left in the sheets or does make its way down to housekeeping, you do not have to worry about being stuck.

I just want to show this in a grander form because it is so small. It is quite a simple concept, and it can be associated. I do need a volunteer.

Chairman WYDEN. Mr. Seifert, even I can see that. Please proceed.

Mr. SEIFERT. OK. Basically the concept is a needle canula, a bored canula inside another sharp canula. This can be used on a syringe, an IV catheter, a phlebotomy needle. The natural action of either injection or the procedure of drawing blood or retracting a catheter advances this blood canula just past the tip while it is still in the patient so that, upon removal from the patient, you no longer have a sharp, exposed point, so it is quite a simple concept, and it does not require manipulation. As a matter of fact, with the catheter and the butterflies, there is no change in behavior whatsoever.

I would like to turn just slightly to a slightly different direction that we touched on briefly, and that is an association for startup businesses. There are a lot of crazy ideas that are running around. We are a pure startup company.

We are slow at this point in time to be able to advance in the marketplace and do have a relatively long list of institutions that are waiting to try our product. If there could be some type of opportunity, say, for the first amount of money that is raised for capital, say the first \$1 million for a startup company that would be able to be directly written off if a company would go under, people would not hesitate to support startup companies.

I don't think that is just an issue associated here with our medical products. I think you will find that for any new technology or company that is trying to get off the ground, raising capital is quite difficult. Small business loans and those type of situations are really unfortunately not available.

If some type of incentive program allowed for those people, that if they took that type of risk, be able to have a dollar for dollar write off, that would be appropriate, and I appreciate the attention to that.

Two last quick issues. There is one other area that involves safety that we do need to address, and I am hoping that this will be picked up possibly by some other committee maybe more directly associated with health issues.

The National Phlebotomy Association is a leading certification organization for phlebotomy in this country, that which is the act of drawing blood. Most people believe that when they go in to have their blood drawn, they are in a position that the person on the other end of that needle is certified and has been properly trained to perform that function. That is not true.

There is no mandatory certification for the act of phlebotomy, which is considered a basic procedure, which we should consider and make some adjustments to in the future, not only for the risk of the patient, but why we are here today, more importantly, so that the healthcare worker knows how to handle the devices properly.

Last, and a comparison I can't help but think of other scenarios, and I feel badly for the healthcare workers in the sense that if today we had a patient who had been walked in here and had been exposed to HIV—and I understand that is a very difficult situation, but we do have a healthcare worker who has that same scenario—we would need a room 5 times the size, and it would be completely filled.

I think that is a pretty sad commentary on our society today that when we are in a position now that we are looking more at the bottom line and not taking care of those who are going to eventually take care of each and every one of us.

Thank you.

[Mr. Seifert's statement, with attachment, may be found in the appendix.]

Chairman WYDEN. Excellent presentation, Mr. Seifert.

On this point with respect to the role these technologies are going to play in our economy, I am very pleased that you would make your central focus beyond the bottom line and right at the heart of our concern, which is health and safety and breaking what I call the first chain link in the transmission of the disease.

My understanding is that there is a lot of potential for our country to create jobs in these new technologies because it is my understanding that right now we are way ahead of most other countries in the world. We have an opportunity to get safer technologies for our healthcare workers, and reduce the incidence of transmission to workers and to patients, and also create jobs by making it more likely that other countries are going to want to come to the United States and get these technologies. Is that correct?

Mr. SEIFERT. That is correct, to the point where we are constantly being approached by European companies and also Japanese companies, not only to market, but to gain the rights for manufacturing of this device.

Chairman WYDEN. So, at this point the Germans and the Japanese, two of our major competitors in the western industrialized world, are not as advanced as we are overall in the field of new needle technologies and the like, and they are coming to you and seeking to enter into contractual arrangements to get some of your products?

Mr. SEIFERT. That is correct.

Chairman WYDEN. Which presumably could lower the price as well in the United States because as you increase the volume of your sales, whether it is through exports or through sales in the United States, over time that dime differential or the few cents that we have been talking about goes down further and further?

Mr. SEIFERT. That is correct, to the point where we are able to project forward, not only on a phlebotomy device, but a catheter device to keep to an increase that, as I mentioned earlier, the cost justification shouldn't even be a discussion.

Chairman WYDEN. Your presentation is very helpful, and we appreciate it.

Chairman WYDEN. Mr. Johnson, we welcome you. The American Hospital Association has been most cooperative with the subcommittee in its inquiry, and we are appreciative of that.

We will make your prepared remarks a part of the record in their entirety. If you could highlight some of your principal concerns, that would be helpful.

TESTIMONY OF WILLIAM H. JOHNSON, CEO, UNIVERSITY OF NEW MEXICO HOSPITAL, ON BEHALF OF AMERICAN HOSPITAL ASSOCIATION [AHA]

Mr. JOHNSON. Thank you very much, Mr. Chairman.

I am William Johnson. I am the chief executive officer of the University of New Mexico Hospital in Albuquerque, New Mexico. Today, I am pleased to be here representing the Association's 5,300 hospital members to address the hazards posed to healthcare workers by needlestick injuries and the adoption of safer medical device technologies by healthcare institutions.

I guess I am also that administrator we have heard about all morning. As chairman of the American Hospital Association's current and Ad Hoc Committee on HIV Infection, as well as the chairman of the committee that developed AHA's initial policies in 1987 related to HIV, I can speak about the long-standing commitment of AHA and its member institutions to enhancing and ensuring worker safety.

We have long worked to enhance this safety by expanding efforts to reduce the risk of occupational injuries to healthcare workers and to minimize their risk to exposure to various bloodborne pathogens. The risk of occupational exposure is a real concern for patients, healthcare workers, and the hospitals.

Strict adherence to the universal precaution minimizes the risks of most exposures to bloodborne pathogens, but universal precautions cannot prevent accidental exposures, particularly injuries that result from needlesticks and other sharp instruments. Healthcare workers who sustain accidental injuries from sharps such as needlesticks face a small, yet nonetheless real, risk of acquiring HIV infection.

The Centers for Disease Control estimates that the risk of such accidental injury is approximately 3 to 4/10ths of a percent for each exposure, and as of October 31, 1991, CDC was aware of 28 healthcare workers who had tested positive for HIV antibodies fol-

lowing a very well-documented occupational exposure to infected blood.

Despite the relatively low risk of transmission and the small number of documented cases of occupationally acquired infection, the devastating consequences of acquiring HIV infection heightens the importance of reducing sharps injuries.

Injury prevention is of paramount concern to hospitals. Although no worker environment can be made 100-percent hazard free, the AHA and its member institutions are committed to protecting healthcare workers and patients with injuries that potentially expose them to various bloodborne infections.

AHA has been in the forefront of efforts to promote worker safety, developing print and video materials to educate hospital personnel about the occupational risks of acquiring bloodborne infections and ways to reduce those risks.

Through these efforts, and they were very early into the HIV infection, AHA developed recommendations updated regularly for hospitals on managing HIV infection in the institutional setting, providing technical guidance developed by AHA's technical panel on infections within hospitals of HIV and hepatitis B virus transmission.

In 1987, we produced a teleconference, a national teleconference, entitled "AIDS: Protecting Hospital Employees." In 1989, with production of "Working Together: Needlestick Prevention," AHA combined a video format with educational print material for its membership.

In 1990, it developed an educational program entitled "Universal Precautions: Multimedia Building Blocks for Prevention and Compliance Training," providing video, slides, and print material. Most recently, a 1990 national effort coordinated with and by the Service Employees International Union developed effective strategies for preventing needlestick injuries.

We have also worked closely with the Occupational Health and Safety Administration to develop appropriate effective standards for the prevention of occupational transmission of the bloodborne pathogen. Rather than mandating specific technologies, the OSHA standards allow hospitals to choose the most appropriate and effective safety control devices for their specific institutional needs.

AHA believes, however, that it is inappropriate for an organization such as ours to endorse a particular commercial product. We do, however, communicate frequently with member hospitals about available technologies to prevent needlestick injuries and methods to evaluate and select appropriate and effective safety devices.

Hospitals evaluate and choose the most appropriate devices for their own use, often through institutional committees composed of infection control experts, clinical staff, labor representatives, and management. Hospitals are faced with a plethora of new products designed to prevent needlestick injuries.

Unfortunately, the reality is that many of these products have never been clinically tested for safety or efficacy. We are encouraged that studies are now under way to evaluate the clinical impact of various safety devices. The State of New York—and I compliment the State of New York—launched a multihospital study of the impact of a variety of needle safe devices last year.

In addition, the New York City Health and Hospitals Corp. is undertaking a separate major evaluation of a variety of safety devices. Data from such studies will be useful to all institutions in selecting safety devices appropriate to their specific institutional needs.

AHA has long advocated the development and implementation of new, effective technologies to reduce the risk of on-the-job injury to healthcare workers. Not enough is being done to provide healthcare institutions with sound, evaluative information.

In the current healthcare economic environment, it would be imprudent to adopt costly technologies that are either ineffective or actually increase worker injuries because they are poorly designed.

The most constructive role the Congress can play is not to mandate use of new technologies but to lend support for increased evaluation efforts, including assessing the safety and cost-effectiveness of particular devices, and stronger coordination of efforts to disseminate results to healthcare workers and practitioners.

Thank you, Mr. Chairman.

[Mr. Johnson's statement may be found in the appendix.]

Chairman WYDEN. Thank you, Mr. Johnson. I will have some questions in a moment.

Why don't we begin with you, Dr. Lashof. I am interested if you can give us any additional information as to why you think there may be underreporting of exposures. Have you all done some research on that point?

Dr. LASHOF. We have no specific research, and much of it is anecdotal, and also my own experience in a previous life when I was more actively involved in hospitals. People tend not to report simple things like a needlestick. They don't take them seriously. There is no requirement that they report them.

Often, staff disconcert part of their daily routine that these things happen. It is only really now with the real understanding of the danger that people are getting more concerned and thinking about reporting, but these things sort of go on, and people are just not responsive to reporting requirements. Hospitals don't push them to report. I think it is just a lack of real initiative on the employee to report them, and I think we have to push on that in the hospital.

Chairman WYDEN. What, in your view, is the most successful and promising way to ensure that these changes are made?

Dr. LASHOF. I think active infectious disease control programs within a hospital, having someone in charge in the hospital of an infectious disease control program who works with the staff to encourage them to report, to make periodic rounds to the nursing stations, talk with the employees, and do your almost daily checks on what has happened on this floor today.

Chairman WYDEN. Is that kind of effort done on a widespread basis today?

Dr. LASHOF. I am afraid I don't have the data on how widespread it is. There are general policies that every hospital is to have an infectious disease control program. How active it is, how sensitive it is, how efficient it is, is something that maybe AHA can answer better than I.

Chairman WYDEN. I am going to ask AHA, but we heard from Mr. Spruill and Ms. Roe here this morning that there were some facilities that were experiencing delays with those aggressive infectious control programs. Any information you have on that point, we will be interested in getting in the days ahead.

Dr. LASHOF. We can try to pursue that for you, Congressman.

Chairman WYDEN. Ms. Chiarello, are you aware of any States that have set up a data tracking system for occupationally acquired infectious diseases? We have a Federal Government that has dragged its feet in terms of trying to get that system set in place. Are there any States that are trying to do it?

Ms. CHIARELLO. I don't personally have that knowledge. I am aware that in certain other occupational health conditions, such as lead exposures, there are State registries for those, but to my knowledge, at least in New York State, we don't have a separate State registry for occupational exposures to infectious diseases.

Chairman WYDEN. It would be very expensive for a State to do it, would it not? It would be a very difficult program, I would assume, for a State to try to set it up. I know, I have been reading stories in The New York Times about the budget situation. Would this be difficult at this point in New York State?

Ms. CHIARELLO. Well, there are existing registries, so in terms of setting up, involvement may already exist on how to set that up. There are ways to be able to support such a system.

I think one of the issues is HIV infection is not reportable in New York State. I think there is a concern on the part of health-care workers to report their exposures, not only report seroconversions, but report exposures.

A lot of what has happened, historically, has been that the healthcare worker has been perceived as personally careless for their injury, and they have been blamed for the injury, so there is not an institutional support to both report the injury.

Concerns about confidentiality, job discrimination, particularly within the institution, I think are a major concern to limit the healthcare worker from reporting seroconversions, so in the State system, we would have to rely on a voluntary reporting.

Chairman WYDEN. That was what I was really interested in, the question of how one would get it off the ground. It struck me that certainly there would be some cost in getting it off the ground. You would then also be in a situation where you had a voluntary program as well for all the work you had done, and get back into some of the problems Dr. Lashof and others talked about, in terms of underreporting, fears, and the like.

Now, you mentioned, in your testimony, available surveillance data for the HIV virus. Are you referring to Centers for Disease Control data or your own data in that regard?

Ms. CHIARELLO. Available information on HIV and healthcare workers. I was referring to the data that was collected in the 1990 survey, and the information we have recently collected as part of the pilot study.

Chairman WYDEN. So, you are talking primarily about your own data?

Ms. CHIARELLO. That is right.

Chairman WYDEN. OK, very good.

Mr. Gianakos, just a couple of questions for you, if I could. From the standpoint of the new standards not encouraging the protection of workers with the use of these new devices and the additional safety that would come about as a result of these new devices, what kind of approaches would you advocate to encourage these kinds of products being used?

Mr. GIANAKOS. Well, for one thing, OSHA is putting teeth into their standards, basically forcing hospitals to comply with regulations associated with using all types of needle devices to protect their healthcare workers.

That may take some manpower by OSHA and maybe something they will have to fund, but it is going to be something they will have to do because compliance is not going to be easily regulated within the hospitals themselves.

Chairman WYDEN. You would advocate what amounts to a regulatory approach, where the Government is going to have to require it, and the Government is going to have to enforce it, and ensure that it is carried out?

Mr. GIANAKOS. In essence, that is correct.

Chairman WYDEN. Let me turn to you, if I could, Mr. Johnson. Mr. Seifert, I asked you some questions as we went along, so I might spare you at this point.

Mr. Johnson, outline for us, if you would, what constitutes, in your mind, a good needlestick injury prevention program.

Mr. JOHNSON. I think it begins with an infection control program in the institution. The Joint Commission on Accreditation of Hospitals does require that that be an assigned duty within an institution.

I believe a needlestick program begins mainly with the senior management staff acknowledging that this is a major issue within the institution and providing the support and the encouragement to implement the program. You then have to have, I think, a very, very well organized employee health program in which employees can, in fact, receive rapid response to a needlestick.

I think in our situation, for example, employee health—that is the emergency room priority for our employees—so you have a number of issues beginning with the CEO saying that it is important, having a defined infection control followed by good employee health.

You then have to have education, and this is a major process of change. The issue was that we have done some direct observation, studies of needlesticks, and find that needlesticks are grossly underreported in an institution.

We most recently, in an operating room study, observed directly 63 needlesticks, only five of which were reported. It was not for any other reason than as Dr. Lashof said, it is part of what you do in the operating room. So, I think that an institution needs to understand the actual incidence of needlesticks within its institution and make reporting that a key portion of the job description of both the employee and the supervisor.

I believe it takes a great deal of management effort to make a program that is to be successful.

Last, it is a responsibility of the institution to review all new products as they are introduced into the institution, look at them

for a variety of activities. We have established criteria as we reviewed in products that first, is it safe for the patient? Does it then increase the safety of the employee?

We need to look at the durability of the product itself, and then we follow that by saying is that company going to be in business in a year so they don't withdraw a product once we have gone through the training process.

Economy is our very last criteria for evaluating new products when they come in for needlestick safety.

Chairman WYDEN. That is a very helpful outline, and let me expand on that. I wrote down what would amount to four components of what you think would be a good program to prevent these injuries from accidental needlesticks.

You cite senior management saying it is a serious issue, a defined infection control system, an education program, and a program where institutions would, on an ongoing basis, review all the new devices so they would look at what would be available.

That strikes me as certainly a sensible step. What percentage of your facilities are engaged in an injury prevention program that implements all four of those points that you are talking about?

Mr. JOHNSON. Well, on a national level, I think that you would find a great deal of disparity between how hospitals would approach this. Clearly, a hospital in rural Wyoming would perhaps not have as much attention as a hospital in the epicenter of New York where this incident would be substantially greater.

I think it is much more difficult to implement a program in rural Idaho than it is in New York City, just because of the perceived threat from the epidemic. I think you will find it will be very different. These are not unusual recommendations that come from the American Hospital Association for our member hospitals to approach this type of program.

Chairman WYDEN. They don't sound to me like unusual recommendations at all. They sound like thoughtful recommendations. What I am interested in is whether, out at the grassroots level, they are actually getting implemented, and I share your view that rural hospitals have unique concerns.

I am one of the few urban Members of Congress who is on the rural health caucus, for example, just to address some of these rural health needs. I am still curious as to what percentage of your members you think would have a program that would, at least in a meaningful way, address these four components that you focus on?

Mr. JOHNSON. I am afraid that I could not answer that in an accurate way. I would hope 100 percent of them. I can't address for my colleagues throughout the country how well they are implementing these programs.

Chairman WYDEN. Well, I think what I would like you to do is to survey your members as to whether they are going forward with a program on those four points because we do have some certainty that it is not 100 percent because Mr. Spruill was here today.

When he brought it to his hospital, his hospital threw away the materials, and it wasn't 100 percent when we heard from Ms. Jean Roe, who told us that a number of the workers didn't get access to the training and education materials. It is not 100 percent.

I will hold the record open on this point because I would like to see whether the bulk of the hospitals in this country do have a meaningful program as it relates to these four areas which you have said are important in terms of preventing accidental needlesticks.

[The information may be found in the appendix.]

Chairman WYDEN. Do any of the panel members have anything further they would like to add? I think all of you have been very helpful and make a lot of very sensible points.

What we have here is a challenge that is going to require cooperation among those who run our healthcare programs, manufacturers, and healthcare policymakers, and we have got to make sure that the kinds of stories that Mr. Spruill and Ms. Roe told today are not the stories of the future, given what Mr. Gianakos said was the increase in the incidence of accidental injury sticks to the point where major insurers say that more of the workers face these injuries than what have been traditional problems, such as back injuries.

I believe that we have an awful lot of work to do, together. All of you have been most cooperative, and we will excuse you at this time.

Chairman WYDEN. Our next panel: Dr. David M. Bell, Centers for Disease Control; Tom Arrowsmith-Lowe, U.S. Food and Drug Administration; and Charles E. Adkins, Occupational Safety and Health Administration.

Gentlemen, can we get all three of you up here, and I gather some of you have some associates who you are going to desire to have testify. Why don't you all be seated at the table, and we will get some of the formalities taken care of. If the staff can get another seat for the good people from the CDC, we will be able to move along.

We have three witnesses, and we have had six people appear at the table. What I am going to do, beginning at my far left, if you, sir, could identify yourself for our reporter, your name and the part of CDC you are associated with.

Dr. MULLAN. My name is Dr. Robert Mullan. I am with the National Institute for Occupational Safety and Health, Centers for Disease Control.

Chairman WYDEN. Very good.

Dr. BELL. I am Dr. David Bell, Chief of the HIV Infections Branch in the Hospital Infections Program, National Center for Infectious Diseases at CDC.

Dr. WEST. I am Dr. David West. I am the Deputy Director of the Office of Device Evaluation within the Center for Devices and Radiological Health, FDA.

Dr. ARROWSMITH-LOWE. I am Dr. Thomas Arrowsmith-Lowe. I am the AIDS coordinator in the Center for Devices and Radiological Health and the Deputy Director of the Office of Health of that center.

Mr. ADKINS. I am Charles Adkins, Director of Health Standards Programs for the Occupational Safety and Health Administration.

Dr. HARWOOD. I am Dr. Susan Harwood. I am Director of the Office of Risk Assessment, and I was the project officer for the bloodborne pathogen standard.

Chairman WYDEN. If you all have no objections, I think what I would like to do in the interest of time is swear all of you because possibly some of you who are not involved in making prepared statements initially might be involved in responding to questions.

Do any of you have any objection to being sworn as a witness for your appearance today?

If you would, please rise and raise your right hand.

[Witnesses sworn.]

Chairman WYDEN. We are going to make your prepared statements a part of the hearing record in their entirety. I want to thank each of your agencies. All of your agencies have been most cooperative in working with the subcommittee on these issues, and we are appreciative of that.

Dr. Bell, why don't we begin with you.

TESTIMONY OF DAVID M. BELL, CHIEF, HIV INFECTIONS BRANCH, HOSPITAL INFECTIONS PROGRAM, NATIONAL CENTER FOR INFECTIOUS DISEASES, PUBLIC HEALTH SERVICE, U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES, ACCOMPANIED BY ROBERT J. MULLAN, MEDICAL OFFICER, HIV ACTIVITY, NATIONAL INSTITUTE FOR OCCUPATIONAL SAFETY AND HEALTH, CENTERS FOR DISEASE CONTROL

Dr. BELL. Thank you, sir. Dr. Mullan and I appreciate this opportunity to present information—

Chairman WYDEN. I have a feeling, Dr. Bell, again we have this horrendous microphone problem. Maybe you could push that up a little bit and speak into it directly. I want folks to be able to hear you.

Dr. BELL. Thank you, sir. Dr. Mullan and I appreciate this opportunity to present information on the hazards of needlestick injuries in healthcare workers and on CDC's activities to prevent these injuries.

Many healthcare workers are at risk for infection with HIV or other bloodborne pathogens due to exposure to infected blood. The greatest risk of infection transmission is from a percutaneous injury. That is a needlestick or cut with a sharp object contaminated with infected blood.

Even if a percutaneous injury does not result in transmission of infection, the injury can be painful and lead to loss of work time and treatment with potentially toxic drugs to try to prevent infection. Also, injured workers and their families may endure considerable stress during followup periods lasting up to 6 months or more as they wait for the results of tests for infection.

In order to assess the risk of HIV infection in healthcare workers and to develop and evaluate recommended preventive measures, CDC conducts surveillance projects and epidemiologic and laboratory studies. With the subcommittee's approval, I would like to submit for the record two recent CDC reports.

One, published in the Journal of the American Medical Association, is a detailed review of CDC surveillance data on healthcare workers with AIDS. The second, published in the American Journal of Medicine, is an up-to-date review of CDC data on the risk and prevention of HIV infection in healthcare workers.

[The information may be found in the appendix as an attachment to testimony.]

Dr. BELL. CDC has in place a formal surveillance system for cases of occupationally acquired HIV infection. Cases are reported to CDC through State and local health departments.

As of December 31, 1991, CDC had received reports of 29 health-care workers in the United States who became infected with HIV after a documented occupational exposure; 27 workers were exposed to HIV infected blood, 1 was exposed to concentrated virus, and 1 was exposed to an unknown fluid.

Of the 29 workers, 24 had percutaneous exposures, 4 had mucocutaneous exposures, that is eyes, nose, mouth, or skin, and 1 worker had both a percutaneous and a mucocutaneous exposure; 18 additional healthcare workers reported that their HIV infection was occupationally acquired. However, transmission of infection after a specific exposure was not documented. Of the 29 workers documented to have occupationally acquired HIV infection, 3 have progressed to develop AIDS.

These data are periodically reported by CDC in a number of publications and presentations, including the journal article that I am submitting for the record today.

I believe that some confusion has arisen in the way that CDC classifies these AIDS case reports in its monthly surveillance bulletin.

In this particular bulletin, detailed cross-tabulations are made of reported AIDS cases according to mode of infection, sex, race, and other parameters. To protect the confidentiality of the three healthcare workers with occupationally acquired AIDS during these detailed cross-tabulations, they are included in a larger category of cases with other or undetermined risk.

Prevention strategies include developing safer medical and dental devices, safer work practices and techniques, and improved personal protective equipment—for example, gloves—as well as appropriate educational programs. Further progress in the prevention of injuries related to common procedures, such as drawing blood or starting an intravenous infusion, will be accomplished primarily by changes in the design of needles and other medical devices.

CDC and other Federal agencies have clearly signaled the need for development and use of safer medical devices in a number of publications in recent years, as detailed in my written testimony.

Numerous new devices are being advertised. However, few of these devices have been evaluated in clinical settings for safety, efficacy, effective control, or effect on patient care. In fiscal year 1991, CDC spent approximately \$1.5 million related to device assessment.

One major event during the coming year will be a national conference on prevention of device-mediated, bloodborne infections, to be cosponsored by CDC, FDA, and OSHA here in Washington in August 1992. This conference will promote the sharing of ideas and establishment of closer working relationships among researchers, device manufacturers, purchasers, users, and Government agencies.

The preliminary program for the conference has just been printed, and with this subcommittee's permission, I would respectfully like to submit the program for the record.

Chairman WYDEN. Without objection so ordered.

Dr. BELL. In summary, CDC believes prevention of bloodborne infection transmission in healthcare settings depends primarily on prevention of percutaneous injuries. When feasible, use of engineering controls, including safer medical devices, is the preferred method of injury prevention. CDC conducts a variety of activities to assist in the development and evaluation of such devices. These efforts will continue in the future in cooperation with other Federal agencies.

Thank you again for the opportunity to appear here today. Dr. Mullan and I would be happy to answer any questions you may have.

Chairman WYDEN. Doctor, we will have some questions in a moment. We thank you.

[Dr. Bell's statement, with attachments, may be found in the appendix.]

Chairman WYDEN. Dr. Lowe, welcome.

TESTIMONY OF THOMAS ARROWSMITH-LOWE, DEPUTY DIRECTOR, OFFICE OF HEALTH AFFAIRS AND AIDS COORDINATOR, FOOD AND DRUG ADMINISTRATION, PUBLIC HEALTH SERVICE, DEPARTMENT OF HEALTH AND HUMAN SERVICES, ACCOMPANIED BY DAVID WEST, DEPUTY DIRECTOR, OFFICE OF DEVICE EVALUATION, CENTER FOR DEVICES AND RADIOLOGICAL HEALTH

Dr. ARROWSMITH-LOWE. Good afternoon, Mr. Chairman. As I mentioned previously, I am Thomas Arrowsmith-Lowe from the Center for Devices and Radiological Health with FDA. I am a healthcare provider at a Washington, DC, clinic where all my patients are infected with HIV. With me today is Dr. David West, Deputy Director of the Office of Device Evaluation in the Center. We are here today to discuss FDA's activities with regard to needlestick injuries.

Healthcare workers may face a risk of infection with a bloodborne pathogen as a result of exposure which occurs in healthcare settings. Percutaneous exposures, where the skin is penetrated by a sharp object, such as a needle contaminated with the blood of another person, pose the greatest risk of bloodborne infection. Bloodborne infections transmitted in the healthcare setting include hepatitis B virus, hepatitis C virus, HIV, and others.

As a part of the public health service effort to combat the AIDS epidemic, FDA has focused regulatory efforts on the role of medical devices which can reduce the risk of HIV transmission, such as condoms and gloves, and on medical devices which serve as a vehicle for transmitting the infection, such as syringes and needles. Syringes and needles used for injecting illegal drugs have been potentially responsible for 45,000 reported cases of AIDS. There have been three cases of AIDS in healthcare workers with documented occupational exposures. In addition to these three cases, CDC has reported today on additional cases of healthcare workers with documented seroconversions after occupational exposure to HIV-infected blood.

FDA is very concerned about the role of syringes in infecting both the small number of individuals infected occupationally and the tens of thousands of individuals infected through IV drug use. This strong concern about the need for products which would reduce the risks of bloodborne infections faced by healthcare workers prompted the FDA to enter discussions with the Centers for Disease Control [CDC] about establishing dialogue between the clinical users of devices and those who manufacture devices.

As you know, the Food and Drug Administration, through our Center, is responsible for ensuring the safety and effectiveness of medical devices, as provided by the Federal Food, Drug, and Cosmetic Act. FDA has cleared for market both products which reduce the risk of injuries from syringes and products which prevent syringes from being reused for injecting drugs. These market clearances were accomplished under the Premarket Notification, or 510(k) process, where the FDA must determine that the product is substantially equivalent to a previously marketed device. FDA looks at descriptive data for the new device, as well as performance data in many cases, and compares those data to the previously marketed device. Approximately 5,000 new products are cleared annually for marketing through the 510(k) process. In fiscal year 1991, 21 needles and syringes were cleared for marketing. To date, over 50 antineedlestick devices have been cleared for marketing through the 510(k) process.

Additionally, FDA has established a policy for the expedited review of Investigational Device Exemption [IDE] and Premarket Approval Applications [PMA's]. This policy is for devices intended for use in diagnosis, therapy, or prevention of life-threatening or severely debilitating illnesses where no satisfactory alternative product is available. Such a process could be applied to the 510(k) process where no alternative product is currently available.

We also have in the center a Division of Small Manufacturers Assistance [DSMA], which received over 7,500 inquiries regarding the marketing of AIDS-related medical devices, including barrier devices, as well as needlestick prevention devices. Most of the antineedlestick devices were developed by small companies, many of which are not fully aware of the FDA regulations in this area. DSMA will be heavily involved in the training sessions that will be incorporated into the August conference, as previously mentioned by Dr. Bell and discussed further in my remarks. In April 1991, FDA received a citizen's petition from the Service Employees International Union. The petition requests that FDA undertake several regulatory and administrative actions, including sponsorship of a public conference on needlestick injuries and methods for reducing them through changes in medical devices. FDA will solicit public comments on this petition through publication of a notice in the Federal Register sometime next week. In that notice, we will note that the FDA is cosponsoring a meeting in August to address the needlestick issue. Furthermore, in the Federal Register response to the petition, FDA will also ask for comments on the approach of establishing a performance standard for needle-bearing devices.

This conference, cosponsored with CDC and the Occupation Safety and Health Administration [OSHA], is designed to establish dialogue about device-mediated, bloodborne infections between

medical device users, manufacturers of devices, regulators of devices, workplace safety, and those who study disease transmission in the work place. FDA, CDC, and OSHA are promoting the conference in the Morbidity and Mortality Weekly Report, through a mailing to health professional organizations and device manufacturers, through information published in health professional journals, and by a mailing to other interested parties.

That concludes my testimony, Mr. Chairman. We will be glad to respond to any questions you may have.

[Dr. Arrowsmith-Lowe's statement may be found in the appendix.]

Chairman WYDEN. Doctor, thank you. I will have some questions.

I wanted to make sure I was exactly clear on your professional activities. You work for the FDA and you run a health program as well?

Dr. ARROWSMITH-LOWE. I work for the FDA, and I am a volunteer clinician at the Whitman-Walker Clinic here in Washington. There are a number of FDA workers who are volunteers with Whitman-Walker Clinic.

Chairman WYDEN. It is to be commended.

Next, we will go to Mr. Adkins.

TESTIMONY OF CHARLES E. ADKINS, DIRECTOR OF HEALTH STANDARDS, OCCUPATIONAL SAFETY AND HEALTH ADMINISTRATION, U.S. DEPARTMENT OF LABOR, AND SUSAN HARWOOD, DIRECTOR, OFFICE OF RISK ASSESSMENT

Mr. ADKINS. Charles Adkins. Thank you, Mr. Chairman.

Thank you for the opportunity to discuss the Occupational Safety and Health Administration's [OSHA] efforts to protect workers from occupational exposure to bloodborne diseases. OSHA is particularly proud of its leadership in promulgating the standard on bloodborne pathogens for several reasons.

The Congress directed OSHA to issue the standard by December 1, 1991, and we met the deadline. The standard represents the agency's response to one of the emerging health issues of the 1990's. By promulgating the bloodborne pathogens standard, OSHA has shown that it can successfully adapt its regulatory structure to new and emerging hazards such as Human Immunodeficiency Virus [HIV].

OSHA began to address the problem of bloodborne diseases as early as 1983 when the agency issued a set of voluntary guidelines designed to reduce the risk of occupational exposure to the Hepatitis B Virus [HBV].

OSHA received petitions requesting a standard for bloodborne diseases in September 1986. On October 30, 1987, the Department of Labor and the Department of Health and Human Services published a Joint Advisory Notice entitled, "Protection Against Occupational Exposure to Hepatitis B Virus and Human Immunodeficiency Virus."

OSHA initiated rulemaking for the bloodborne standard with an Advance Notice of Proposed Rulemaking in November 1987 and issued the final standard in December 1991. OSHA reviewed more than 3,000 written comments and received testimony from more

than 400 participants in public hearings which were held in Washington, DC, Chicago, New York, Miami, and San Francisco.

The standard applies to any employer with employees who may reasonably be anticipated to come into contact with human blood or other potentially infectious materials while performing duties at work. It covers almost 5 million workers, most of whom are employed in healthcare facilities. OSHA estimates that the regulation will prevent approximately 200 deaths and approximately 9,000 hepatitis B infections each year.

The standard is based on the adoption of the Centers for Disease Control's universal precautions as a method of infection control. This approach assumes that all human blood, certain body fluids, and other potentially infectious materials can be sources of infectious disease. To minimize employees' risk of contracting bloodborne diseases, employers are required to use a combination of engineering controls, work practices, personal protective equipment, training, the hepatitis B vaccine, and medical followup after an exposure incident. Employers must develop hazard abatement measures which best suit the workplace and accomplish the objective of protecting workers from contact with blood or other potentially infectious materials.

Employers must first develop an exposure control program that identifies employees who have occupational exposure, occupational exposure to blood or other potentially infectious materials. Employers are also required to develop procedures to evaluate the circumstances surrounding exposure incidents such as needlesticks. By evaluating each exposure incident, the employer can take steps to prevent further exposures from occurring. Appropriate medical followup and counseling must be made available to employees who have an exposure incident.

The standard requires that each employer offer the hepatitis B vaccine, at no cost, to all employees who are exposed through their work to blood and other potentially infectious materials. Employees who choose not to accept the vaccine must sign a declination form. If they later change their minds, they may still receive the vaccine.

Employers must institute engineering and work practice controls as the primary means of eliminating occupational exposure to bloodborne pathogens. In general, engineering controls, such as self-sheathing needles or biosafety cabinets, isolate or remove the hazard. When occupational exposure in the workplace remains after institution of engineering controls and work practices, employers must provide personal protective equipment as supplemental protection.

Needlesticks are a serious danger to healthcare workers. The risk of contracting a hepatitis B infection following exposure with a needle contaminated with blood from an individual infected by HBV is between 60 and 300 per 1,000. Handling and discarding of needles warrants special attention. The standard requires that contaminated needles and other contaminated sharp instruments not be removed or recapped unless the employer can demonstrate that no alternative is feasible or that such action is required for a specific medical procedure. If recapping is necessary, it must be done by a mechanical device or by a one-handed method. Immediately, or as soon as possible after use, contaminated reusable sharps must

be placed in containers that are puncture-resistant, leakproof, and labeled or color-coded.

Information and training are essential components of the standard. To ensure that employees receive adequate warning about the hazards of bloodborne pathogens, employers are required to provide information through biohazard labels, signs, and training. Employers must also ensure that all employees participate in a training program when they are first assigned to a task involving exposure to blood or other potentially infectious materials and at least annual thereafter. The training program must deal with all aspects of the standard and must include an opportunity for questions and answers. All trainers must be knowledgeable about the standard.

The bloodborne pathogens standard will become effective on March 6, 1992. By May 5, employers must complete their exposure control plans. Initial training must be given by June 4, and all other provisions will be in effect, by July 7, 1992.

OSHA already has considerable enforcement experience in the healthcare industry. Since 1987, OSHA has enforced the "General Duty Clause" of the Occupational Safety and Health Act, as well as certain general industry standards, in the healthcare sector. In the past 2 years, OSHA conducted 767 inspections for bloodborne hazards and found more than 3,500 violations.

We are preparing OSHA's Compliance Safety and Health Officers to enforce the new standard. A compliance directive, describing the proper way to conduct healthcare inspections will be issued. OSHA's Training Institute, which instructs Federal and State compliance officers, provides a course on Biohazards, which includes instruction on the bloodborne standard. In addition, the Training Institute is conducting "Train-the-Trainer" sessions on the bloodborne standard and its enforcement directive this month. The instruction is designed to allow Federal and State personnel to provide instruction to others. Approximately 150 compliance officers will participate in the sessions.

Mr. Chairman, there was an error in transmission. We will train 150 compliance officers who will go forth and train several thousand more compliance officers. We do have several thousand compliance officers in the States, as well as the Federal Programs.

The bloodborne standard will be effective in protecting workers only if employers and employees are aware of its provisions and knowledgeable about how to comply. To provide assistance, OSHA has initiated an outreach program on the standard. The outreach program includes videotape, information packets, fact sheets, booklets, and a conference. On August 17-19, 1992, the Centers for Disease Control, the Food and Drug Administration, and OSHA will cosponsor a National Conference on Prevention of Device-Mediated Bloodborne Infections. The conference will focus attention on injuries from sharps and the safety of medical devices and instruments in all healthcare settings. We estimate there will be between 500 to 700 participants.

Mr. Chairman, this concludes my prepared statement. We believe that the Department and OSHA's leadership in issuing the standard on bloodborne pathogens will have a far-reaching impact in protecting workers, not only because of its particular provisions,

but because it may serve as a prototype for our approach to solving other health hazards which emerge in the years to come.

I will be pleased to answer any questions

[Mr. Adkins' statement, with attachment, may be found in the appendix.]

Chairman WYDEN. Thank you very much, Mr. Adkins.

As I say, all of your agencies have been cooperative with the subcommittee and its inquiry. I have to tell you, I am very troubled about where we are at this point. Mr. Spruill has told us that he works in the laundry room, and all these contaminated materials are coming down the laundry chute, sharps and needles, and what we have is a situation where we are having a lot of conferences to talk about it.

Ms. Roe tells about the problem of people not getting training and very serious kinds of public health issues, and we say we are having some dialogue with companies, and again still more conferences.

I think what we have to do is change the course here and set about these new policies. I have a few questions I want to ask as it would relate to doing it.

Dr. Jagger made what struck me as a number of very important points. Some of you may not have been here.

One of the points she raised was that she felt there was very extensive and unnecessary use of needles generally, particularly as it relates to catheter treatments, and IV services as it relates to the connective parts of these medical device programs.

Do you believe that is the case, Dr. Bell?

Dr. BELL. Yes, sir; I do.

Chairman WYDEN. OK.

Dr. Lowe, do you believe that right now there is extensive and unnecessary use of needles in areas like IV's and catheters, as Dr. Jagger said?

Dr. ARROWSMITH-LOWE. The information that is available to me personally would indicate there are products that are being used on the market that could have actually no sharp associated with them and be just as functional.

Chairman WYDEN. I will say that that is yes; correct?

Dr. ARROWSMITH-LOWE. Correct.

Chairman WYDEN. All right.

Mr. Adkins, do you believe, as Dr. Jagger does, that there is extensive and unnecessary use of needles, possibly as high as 50 percent as it relates to IV's?

Mr. ADKINS. I am not sure OSHA has a position. We would not disagree with what has been said at this table.

Chairman WYDEN. Dr. Jagger says there are a number of companies, major device companies, that are essentially using these old outdated products. These are not little kinds of concerns, but major concerns very prominent in the field.

Dr. Bell, do you think that is the case?

Dr. BELL. I think that is likely to be the case.

The reason I am hesitating is that before one declares a product to be outdated, one needs to have a good idea of what the replacement is. We firmly believe that the answer to the problem of needlestick injuries, particularly on wards and outpatient settings—I

might add this is very different from the operating room setting, which is a whole other problem—we firmly believe the answer to the problem of needlestick injuries during these commonly performed procedures is going to be improvements in the device itself, rather than, for example, blaming the worker or telling them to be more careful. It is just that these new devices do need to be evaluated to make sure that they do, in fact, live up to their billing.

I am familiar with an intravenous insertion device, for example, that is seemingly safer to use for the worker. On the other hand, you can't tell if the needle is in the vein or not when you are trying to place the device. The patient then would run the risk of getting stuck more often.

I am not trying to avoid the question. This is clearly the answer to the problem. What I am saying is, we need more evaluation of some of these devices as well.

Chairman WYDEN. I think it is a fair comment. I am not even on to the new products yet. I am still talking about the old products, which is what Dr. Jagger says point-blank, citing at least three major companies as categorically ignoring safety concerns. Essentially, these would be older outdated products.

You said you thought that was likely the case, but you don't have any extensive data on it, I gather. Is that correct?

Dr. BELL. Yes.

Chairman WYDEN. Dr. Lowe, do you think Dr. Jagger is essentially correct on the point that several of these major companies have not been sufficiently sensitive to the safety concerns with their products?

Dr. ARROWSMITH-LOWE. There are products on the market that reflect both the old technology of having syringes and needles which are covered, after use, by the workers themselves, as well as technologies that are on the market which incorporate newer designs, which reduce the likelihood that providing protection over the sharp will actually injure the user of the product. Both new technology and old technology are available on the market.

Chairman WYDEN. I know new technology and old technology are available on the market.

What I am interested in is whether or not the FDA thinks Dr. Jagger is on target with respect to these major companies giving short shrift to safety concerns with their products.

Dr. ARROWSMITH-LOWE. I don't have any information to indicate the companies have been insensitive to that.

Chairman WYDEN. Any opinion on this, Mr. Adkins?

Mr. ADKINS. No, sir; OSHA would not have an opinion on that. The OSHA standard requires employers to comply with the standard and protect employers or eliminate the exposures. In doing so, we hope that the standard is a technology-producing standard.

We do have a hierarchy of controls that we expect employers to implement, and that includes eliminating the hazards to begin with, rather than using protective devices, if at all feasible.

Chairman WYDEN. I would like to ask, particularly, CDC and FDA to follow up on these comments that were made by Dr. Jagger. Because when Dr. Bell said that it is likely that there are products out there that raise serious safety concerns, if that is the

case, I want to know what the Federal Government is doing about it.

We have seen the Federal Government, in other areas, move to take these kinds of products that are not state-of-the-art safety products off the market. What I want to know is whether the Government thinks that there are products out there that are less than safe and certainly aren't state-of-the-art, and if that is the case, what is going to be done about it.

Dr. Bell, can you do that and have that information to us, say within a couple of weeks?

Dr. BELL. I can do my best to meet that request.

I do want to say that we at CDC have a great deal of respect for Dr. Jagger and her work. She is one of our valued consultants, and we have funded part of her work as well. We value her opinions very much.

[The information may be found in the appendix.]

Chairman WYDEN. Well, I think that reaffirms my concern here. That is why I want you all to move fast.

Dr. Jagger, who you all say you value her opinions very much, says, and I quote, "Others with respect to companies have categorically ignored the safety concerns raised by their products," and she names three major companies. I would like to see what CDC thinks of the products that those companies are making, and I would like that information within the next couple of weeks.

[The information may be found in the appendix.]

Dr. BELL. Let me just clarify also that we don't have programs in place to evaluate specific commercial devices of this nature. I apologize if I implied that we ever did.

Our activities have been, number one, to collect information on the circumstances under which needlestick injuries occur in different areas of the hospital, including the devices with which they are associated. Then, in terms of trying to facilitate the evaluation of better devices, what we normally do would be to establish a relationship with an impartial group—for example, a university or a health department—to fund them and work with them collaboratively for them to develop evaluation criteria and for them to assess specific devices. For us to get involved with a specific commercial product risks ethical dilemmas and conflicts of interest.

So, I would not want you to think that in the near future we could give you a report on the few different devices that Dr. Jagger has criticized.

Chairman WYDEN. I assume that you are going to work with the folks at the FDA, because your organization is involved in research in this area. The FDA has authority with respect to devices.

Dr. Jagger makes a very serious point here, and I guess the last question I would like to address on this point is if the FDA, when you all work with the CDC in response to my inquiry, finds that these products are ignoring safety concerns, do you have the authority to pull them off the market?

Dr. ARROWSMITH-LOWE. I will refer to Dr. West on this. I have a comment I would like to make as well.

Dr. WEST. When you were pressing the question before, I thought there were two questions you were asking. One was, there were

specific companies ignoring safety issues or safety designs. I thought that was one of the issues.

We don't have access to the corporate mind. We don't know what they are thinking; we don't know what they are ignoring. We can only respond to what they bring to us.

In terms of devices, I think the second question was, can FDA remove unsafe devices. Yes; FDA can remove unsafe devices if FDA can prove the devices are misbranded or adulterated. Many of these sharps, needles, and syringes, have been on the market for decades.

The risks have been in the medical profession for decades. It would be very difficult, as a legal matter, for FDA to proclaim that needles and syringes which enjoyed market access before 1976 could be denied market access now. In other words, we would have to prove that they are misbranded or adulterated. We could try that, but I think whether we succeeded or not would have to be sorted out in the courts.

Chairman WYDEN. This certainly sounds like a legal thicket, and knowing enough about FDA law, I am sure that is the case. It seems to me if we have people, like Dr. Jagger, who say point-blank that companies are ignoring safety concerns raised by their products, we ought to have a system for dealing with it. We ought to make sure either those safety concerns are addressed or the products are taken off the market.

We will work with you and plan to pursue this very vigorously, because I find this troubling, first, that we have this situation in an area where you are talking about the transmission of infectious diseases, and, second, it seems Government is almost muscle bound or caught up in its own kind of processes to try to deal with it.

We will want to ask you some further questions about this, possibly in writing, to nail this down, but I want those issues looked at, and I want this committee to get a report as to what the two agencies, the CDC and the FDA believe is appropriate to deal with the very serious issues that have been raised by Dr. Jagger.

[The information may be found in the appendix.]

Chairman WYDEN. The other area that I had for you, Dr. Bell, with respect to CDC, is that I think it is very confusing at this point as to whether or not separate statistical reports are kept for occupational transmission of the AIDS virus. Are those reports kept or aren't they?

Dr. BELL. Yes; absolutely. We have a formal surveillance system that collects information provided to us by State and local health departments on cases of occupationally acquired HIV infection.

At the moment, we have 29 documented cases in this system, resulting from a documented occupational exposure, and we have 18 other cases in which the State health department reported the worker, but the specific exposure was not documented. We absolutely do have this system in place, and we publish its results periodically.

I think one of the sources of confusion has been that the first system that we had in place was for AIDS cases. Actually, for this particular purpose, looking at AIDS cases is not good enough, because most of the occupationally acquired infections have not yet

progressed to AIDS. It is really better to look at this other system that we have rather recently instituted.

Chairman WYDEN. Well, I have, Doctor, the HIV-AIDS surveillance report for January 1992, and as it relates to adults, I don't see anything about occupational transmission. I see, in this order: Men who have sex with men; injecting drug use; men who have sex with men and inject drugs; sex with injecting drug users; sex with bisexual males; sex with person with hemophilia; category—I can't even really make out—born in Pattern Two country; sex with person born in Pattern Two country; sex with transfusion recipient with HIV infection; sex with HIV person; risk not specified; receipt of blood or tissue; other undetermined.

There is nothing here that relates to what we have been talking about today, which is a separate statistical tracking for occupational transmission.

Now is the committee missing something in this regard?

Dr. BELL. It is a little confusing. Let me try to clarify it, if I might.

Dr. BELL. Every month, the CDC puts out a monthly surveillance report. It sounds like you have part of that report there. The table you are quoting from doesn't mention healthcare settings or healthcare workers in particular, but toward the end of that report there are other tables and figures that summarize healthcare workers with AIDS and cases where infection was acquired in the healthcare setting.

Now, there are two points: One, we do have this system, and we do update and publish this data; and one of the reports I am submitting for the record will tell you everything you want to know.

But the other point is, you have to realize that right now there are only three cases of healthcare workers who acquired HIV from documented exposures and who also progressed to develop AIDS. We have to be very careful when we deal with relatively small numbers of cases so that when we cross-tabulate them in one way or another by sex, race, and so on that we don't inadvertently identify them. So, when those cases are put in tabular form for cross-tabulation, they are lumped for their own protection within a much larger group.

But it does specify elsewhere in the report that there are these cases who acquired it in the healthcare setting.

Chairman WYDEN. It is going to get a little more confusing here in a second, because the categories that I have read you add up to 100 percent. All of the categories that I read you, when you take the individual percentages, add up to 100 percent. So, we have 100 percent of the exposure categories, and there is nothing there for occupational exposure.

I am very interested in seeing your separate list that you say exists for occupational exposure, because when we see that, we are going to have to do some reconciling of these two lists, because the list I gave you adds up to 100 percent according to your figures, there in the bottom, right-hand corner.

Dr. BELL. But that includes the other undetermined group, which is a few percent. You see, if you are only talking about three healthcare workers—three as a percentage of 200,000—

Chairman WYDEN. Those three, what is the situation with those three?

Dr. BELL. Three healthcare workers who have AIDS, who got infected with HIV on the job; there are three of them. In the table you mentioned, they are included under the other "undetermined" to protect their confidentiality. That is why the numbers do add up to 100 percent, because they are included in this larger category.

Chairman WYDEN. We will hold the record open to look at any other information you might have. I have to tell you, I got 100 percent. The adult exposure figures, and these come from you all, add up to 100 percent, and I am puzzled as to how something else can exist that isn't listed here without it adding up to over 100 percent.

Dr. BELL. Do you not have an "other undetermined" on the bottom?

Chairman WYDEN. Yes.

Dr. BELL. The healthcare workers are included in there.

Chairman WYDEN. There is a separate list for them somewhere?

Dr. BELL. They are described in a footnote. It should be toward the end of the document. I actually have the December surveillance report. It happens to be on page 16. I think in January it might be on page 18. It is toward the end.

Chairman WYDEN. Everyone else today who represents those who work in this field is working for a separate statistical tracking system for occupational transmission of the virus and seems to have the same concern, that it is impossible to glean that from your materials, so we will certainly want to look at them and work with you to get this done.

The information may be found in the appendix.]

Chairman WYDEN. The other point that concerned me dealt with the discrepancy between figures as to the number of healthcare workers who have gotten the HIV virus. I think last Sunday, Dr. James Curran of CDC cited a much larger number of individuals who have the HIV transmission due to needlestick injuries. We are very interested in trying to get some clear consistency in terms of making out all these numbers.

In fact, even in your testimony today, at page 4 you say as of December 31, 1991, 29 workers in the United States had seroconversions to HIV after a documented occupational exposure. That is your testimony at page 4.

Is it 29; is it 3? Is it the number Dr. Curran seemed to cite in the New York Times last week with respect to needlesticks? What can you tell us that can make some sense out of these numbers that all seem to be hard to follow and add up?

Dr. BELL. I am sorry. Let me try.

We have gotten reports of 29 healthcare workers in the United States who acquired HIV infection after a documented occupational exposure. There is a smoking needle, so to speak. They got it, and we know they got it from that; they developed infection as a result of that exposure. There are another 18 healthcare workers who were reported in the system as having acquired infection occupationally, but we don't have a smoking needle.

Now, as you know, AIDS is the end stage of HIV infection. Only three of those who I just mentioned have actually gone all the way

to develop AIDS. So, 29 plus 18 is 47. That includes three who have gone on to develop AIDS.

It is more informative to look at the ones who acquired HIV infection, regardless of whether they have progressed to AIDS or not. So, the three is not really the important number. The important number is the 29 documented and the other 18.

Now, I am not sure exactly what you are referring to, remarks by Dr. Curran, but these are our surveillance data.

Chairman WYDEN. I have to tell you, it is really hard to sort through the discrepancy in these numbers, and I am going to ask the staff to work with you. For the record, we can get CDC's best and most current assessment, whether it is 3 or 29 or 60, or whatever the number is. We will try to do that so that the record of this hearing will reflect the most current information.

[The information may be found in the appendix.]

Chairman WYDEN. I have a question for you, Dr. Lowe, if I could. FDA is having a dialogue with the companies that are involved in these technologies. To what end is this dialogue? What is the point of this exercise?

Dr. ARROWSMITH-LOWE. As a part of the public health service effort to address the specific issue of the occupational transmission of HIV, the FDA and CDC began discussions about what methods could we use to try to address this; and there were a number of things which came to mind. One of those things which came to mind was to try to establish a dialogue through a conference between the people who are put at risk and the people who are marketing the devices, so that, somehow, the people who are at risk could get the message across, and we could assure the people who were manufacturing and marketing the devices would hear the messages from the healthcare workers about the type of risks they were facing, the problems they were seeing with devices.

Interestingly, Dr. Jagger is one of the people who will be helping us at that particular meeting, getting the point across to manufacturers about the kind of problems that are existing with the devices.

It is establishment of some dialogue between healthcare workers and the industry to try to reach that end, where there are safer products that are available.

Chairman WYDEN. I am interested in seeing the results, but I have to tell you that I think this is somewhat curious as an exercise in getting the message out. The message is out. Mr. Spruill and Ms. Jean Roe and the other health workers feel they want these new technologies.

You have companies coming here and saying they would like to have access to markets and have the opportunity to sell their devices, and go further and say that people from Europe are coming and wanting to get these devices as well. It seems to me about everybody has got the message except the government agencies that are doing very little except holding occasional conferences to promote these technologies.

I think your conference is great, and we are anxious to hear about the results. That doesn't strike me as a very aggressive program to advance new technologies, to have a conference. The point is to get the message to the manufacturers and various other

people. The message ought to go to people who are at your agencies, because I think that is where the bottleneck is and where we need to work.

Now, with respect to you folks at OSHA, we had comment from a number of the organizations representing the workers about the length of time it took to develop a program to deal with even the modest standard, the bloodborne infection hazard standard. It doesn't even get to the sharps and needles that the workers were concerned about.

Why did it take so long to come up with this standard? I guess you all started in the early 1980's.

Mr. ADKINS. Mr. Chairman, late 1980's, really 1987 or so.

Chairman WYDEN. What was going on in 1983?

Mr. ADKINS. We issued a set of voluntary guidelines to health-care facilities designed to reduce occupational exposure to hepatitis B virus. It was not a regulation, it was a suggestion that these things be done.

Chairman WYDEN. So, you issued this suggestion in 1983, and then until 1987, things just kind of crept along, and then in 1987 you got serious about it?

Mr. ADKINS. No; they didn't creep along.

Chairman WYDEN. What happened between 1983 and 1987?

Mr. ADKINS. If we had complaints, or if we inspected facilities where there might be occupational exposure to hepatitis B, we looked at the employers conformance with those guidelines.

We enforced a number of existing standards including rules for protective clothing, housekeeping, tugging, waste disposal, and our general duty clause, Section 5(a)(1) of the Occupational Safety and Health Act, all of which were being enforced during this period of time.

In September 1986, we were petitioned to develop a rule, a specific rule for bloodborne pathogens, and we initiated the rulemaking process. The process of OSHA rulemaking, as you well know, is a public process. This rulemaking process generated the largest record that OSHA has ever generated on any rulemaking. The record must be reviewed and analyzed by the staff within OSHA before the rule is finalized.

We conducted public hearings in five different cities around the country. The longest was about 3 weeks long and the shortest was a little less than a week long. All of this is time consuming. I can assure you Dr. Harwood and her staff had their elbows to the grindstone during this whole period of time completing that rule.

There was a time during the rulemaking process when we began to get a lot of letters from trade associations, and those were coming through Congress and coming to us. We were getting as many as 150 letters a day which we had to respond to. We have a mandate to respond. The same people were developing the rule that were responding to those letters.

So, the rulemaking process at its best, with the public input, is going to take 3 to 5 years to get a rule through the process to complete the feasibility determination, to complete the economic analysis, and to have the public dialogue that we want to have in the process.

Chairman WYDEN. Well, everybody knows that Government moves slowly, but I think what we heard from the workers is that there is no time to wait. I mean, how long is it going to take to get in place rules and regulations to deal with the kind of thing Mr. Spruill talked about this morning when he said that hundreds of sharps and needles that were contaminated were hurtling into the laundry room.

Ms. Roe said that people at her hospital weren't getting the training and the education they needed. How much longer is it going to take to deal with the sharps, the needles, and the education requirements?

Mr. ADKINS. Some of the items that were described this morning were in violation of existing rules at the time. I think with regard to Mr. Spruill's comment—in Michigan, which is a State Plan State, the State was involved. The kind of practice described has not been accepted or, better yet, ignored by the health and safety groups for several years.

Throughout the development of this bloodborne pathogens rule, we had a compliance directive in place, and we were conducting inspections as I indicated in my testimony. We conducted several hundred inspections in the last couple of years, enforcing the existing standards, that basically were the same as what the bloodborne standard is going to require, but it had a different approach to enforcement.

Chairman WYDEN. Some of what Mr. Spruill and Ms. Roe have talked about today is already a violation of the law.

Mr. ADKINS. Exactly right.

Chairman WYDEN. Tell us if you would, how many enforcement actions OSHA has brought in this area. Can you give us some information as to the number of legal enforcement actions, for the kind of violations they talked about, that have been brought?

Mr. ADKINS. We have data which show a number of inspections. As I indicated, OSHA conducted some 767 inspections in the last 2 years. There were more than 3,500 violations alleged as a result of those inspections. We have that data we can provide to you from past years.

Most of these inspections involve compliance with existing regulations.

For example, we have a regulation that has been on the books since 1971, that requires protection.

Chairman WYDEN. How many citations were issued for what you said Mr. Spruill has talked about, that constitutes a violation of the rules?

Mr. ADKINS. You are asking for a specific violation of a specific standard. I only have data on generalities today. If that particular violation is a violation of a standard, one of many standards that we have, we can provide you with information on how many times that particular standard was cited.

I can tell you that we conducted so many inspections, we issued so many citations for violations, and they may have been violations of personal protective equipment, they may have been violations for not providing the vaccine to employees, they may have been violations concerning the way people were handling materials, like the laundry coming down the chute with the needles, and so forth.

We can identify those in our management information system, but I don't have that information available to me today. I would be happy to make it available to you.

[The information may be found in the appendix.]

Chairman WYDEN. This is a hearing to investigate what the Government is doing to address these problems of the transmission of the HIV virus and hepatitis B, which kill several hundred people a year as a result of accidental needlesticks. You are saying you don't have any information with respect to citations on this point?

Mr. ADKINS. No, sir; I said I did not have it with me. I said we have a management information system.

I can tell you in fiscal year 1990 we conducted 343 inspections, 303 of those were health inspections, 64 percent of the inspections were unprogrammed inspections, including complaints and referrals. I can tell those inspections resulted in 18 willful violations, 31 repeat citations, 1,094 serious violations, but I cannot tell you that one of those 1,094 was from sharps or from protective gloves. Today, I cannot tell you that.

I can get that information for you and break that number down.

Chairman WYDEN. We will hold the record open on that point.

[The information may be found in the appendix.]

Chairman WYDEN. The last question is for you, Mr. Adkins. How frequently would a typical medical program, a major clinic, major hospital, or health maintenance organization, expect to see an OSHA person who was inquiring as to their procedures for preventing bloodborne infection?

Mr. ADKINS. How frequently?

Chairman WYDEN. Would they come once every 2 years, once every 4 years? What would be the frequency?

Mr. ADKINS. Depending on the situation, if we received a complaint from an employee in that workplace, we would be out there as many times as we received those complaints. We have an inspection scheduling system which requires us to inspect high-hazard industries first on a random selection basis. We have conducted some special emphasis programs for bloodborne pathogens.

I cannot tell you that a dentist's office would be inspected every 3 years or every 5 years. It is not on the schedule to be conducted that way.

Major healthcare facilities would be inspected for other reasons. When we are in those facilities, we will conduct the bloodborne pathogens inspection also.

Chairman WYDEN. That is encouraging. What you are saying is that you will be in these facilities regularly for other purposes, and now, because of the seriousness of the problem, you also look at their practices as it relates to infection control for bloodborne disease.

Mr. ADKINS. If we enter a worksite where there might be healthcare providers working, we will look at the bloodborne pathogens. If an employee complained about a punch press, and there was a medical facility there, we would look at that.

Chairman WYDEN. You all have been very patient. I have asked some questions about matters that concern me, because it seems to me we do have an opportunity, for what amounts to a few cents, to provide an extra measure of safety. I have to tell you that, at best,

my conclusion is that Government does not have a comprehensive program to advance these technologies.

I think it is high time. Other countries are coming to the United States, wanting to purchase these products. Healthcare workers have to live in fear that a needle may be stuck under some gauze or something like that and they are going to be stuck. That is just not acceptable.

It is going to take more than conferences. I am going to want a report from Dr. Bell and Dr. Lowe on the matter that Dr. Jagger brought up with respect to the practices of several of the companies. We have already asked the hospitals to survey their members as to whether or not they are engaged in those practices that the Hospital Association thinks constitutes an effective program to prevent accidental needlesticks; and it seems to me that what this comes down to is that we cannot afford not to have these programs in place.

It is going to take more than gloves and the kinds of clothing that has been required to date. It is going to take aggressive action to reduce accidental needlestick injuries.

We are anxious to work with all of you cooperatively, and I want to note, despite my comments here, that all of your agencies have been cooperative in this inquiry. Let me give you the opportunity to add anything further if you choose. Do any of you have anything you would like to add further?

All right, the subcommittee is adjourned.

[Whereupon, at 2:00 p.m., the subcommittee was adjourned, subject to the call of the Chair.]

APPENDIX

OPENING STATEMENT
BEFORE THE
SUBCOMMITTEE ON REGULATION, BUSINESS OPPORTUNITIES
AND ENERGY

PREVENTING THE SPREAD OF BLOODBORNE DISEASE VIA
ACCIDENTAL NEEDLESTICKS:
GOVERNMENT REGULATORS, MEDICAL PROVIDERS, IGNORE NEW
TECHNOLOGIES WHICH COULD SAVE WORKERS FROM
SERIOUS ILLNESS AND DEATH

REP. RON WYDEN
February 7, 1992

Today, the Subcommittee on Regulation, Business Opportunities & Energy continues an inquiry begun almost five years ago into the U.S. health industry's efforts to control the AIDS-HIV epidemic. Our focus is whether American healthcare workers are adequately protected in the workplace from exposure to AIDS and other bloodborne diseases like hepatitis B. After careful examination, we can only conclude that much remains to be done.

More than five million healthcare workers are exposed daily to deadly infectious disease. When the safety of these workers is in question, their patients will continue to doubt the ability of our healthcare delivery system to protect the public health. Reduce needlestick injuries, and you break the first critical chain-link in the transmission of infectious disease.

At issue today is the problem of infection control among the frontliners fighting disease -- the doctors, nurses, trained technicians and support workers who staff our hospitals, clinics and physicians' offices.

And, what we see emerging are three pictures. One is of great professional heroism -- individuals who take unavoidable risks, daily, to treat people whose contagion could cause serious illness or death for the healer. The second picture is of system failure. Most healthcare providers are moving at a snail's pace in acquiring and using new, safer technologies readily available to protect healthcare workers from the accidental spread of disease.

The third and most harrowing picture is of a lack of federal leadership. After six years of bureaucratic wrestling to devise a bloodborne disease standard for occupational safety in this high-risk arena, the government next month will implement a safety rule that is full of holes. Specifically, the Chair is concerned that this standard does not go beyond the use of high-strength gloves and masks in surgery. No standard has been written to demand use of safer needles, connective devices and IV lines -- the source of real disease risk to workers.

Page Two

There are an estimated one-million-plus accidental needlesticks per year sustained by public health workers from surgeons to laborers in the laundry room. These accidents have resulted in thousands of cases of hepatitis B, a disease which claims the lives of approximately 300 health service workers per year.

In addition, there is solid documentation of the increasing number of AIDS-HIV transmission cases among healthcare workers from these accidental sticks. The Centers for Disease Control readily admits that the number of documented cases probably is far outnumbered by unreported and undocumented instances of transmission.

The cost of these injuries is staggering. Accidents from needles cost the U.S. health system a whopping \$750 million a year just to test workers who report sticks!

And it's not just AIDS and hepatitis B. Health workers also face measurable risk of contracting, from contaminated needles, diseases such as Delta hepatitis, syphilis and even malaria.

The subcommittee has found that by utilizing new technologies, including syringes, IV tubes and connective devices, up to HALF of the accidental sticks could be prevented each year.

Why isn't this state-of-the-art new technology being fully deployed? The new devices are marketed by several companies. They have Food and Drug Administration approval. The hospitals using them report good results.

As we shall hear first-hand from workers, today, infections from these accidents have had a devastating impact on their lives.

Why aren't more employers buying these safer devices? The reasons appear to be two-fold. First, these devices are slightly more expensive than older, less-safe needles and connective hardware. As one device manufacturer already has told the subcommittee, virtually every hospital purchasing agent in the country is taking a "wait-and-see" approach to new, safer devices.

This is a short-sighted approach. The subcommittee staff has documented both short-term and long-term savings for hospitals. Use of safer devices will save money in reducing mandated post-stick testing, alone. Add-in treatment costs for those who actually come down with these illnesses, and it's quite clear that safety pays.

Beyond the cost issues, these new technologies ought to be standard equipment simply because it's right,

Page Three

The federal agencies charged by Congress with protection of health care workers have failed to demand that safer needles become that industry standard.

The Occupational Safety and Health Administration (OSHA) Bloodborne Disease Standard -- targeted at curbing transmission of infectious disease in the workplace -- may be a beginning. But as the Chair has noted, this standard doesn't go beyond masks, gloves and other "shields." Safer needles should be required.

More importantly, serious questions remain as to OSHA's ability to enforce even their modest standard. The Chair notes that there are only 140 federal inspectors for more than 6,000 U.S. hospitals.

The Centers for Disease Control's statistical tracking of infectious disease too often misses the boat. They can't say, with assurance, how many healthcare workers are at risk, or what kind of accidents they experience.

We will hear testimony today from a healthcare worker who contracted the HIV virus from a needlestick injury. But you'd never find her among the statistics kept by CDC, because CDC has no tracking plan specific to healthcare workers. And this means both numbers of infected healthcare workers, and the way in which they were infected -- important information in battling this disease -- remain unknowns.

This is not acceptable. Clearly, the CDC needs a tracking system that monitors healthcare workers like our witness with HIV.

The Bush administration has declared war on AIDS. But when it comes time to fight with new technologies, agencies like the FDA are still in their barracks. After initially approving many of these safer devices, the FDA and other federal agencies have done little to promote their use.

The bottom line is that we -- caregivers, hospitals, the government -- must do more, together, to break the first link in the chain of infectious disease transmission. State-of-the-art protection can significantly reduce the spread of blood-borne disease among healthcare workers, and all Americans will be safer as a result.

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January 16, 1992

TO: Ron Wyden, Chairman, Subcommittee on Regulation,
Business Opportunities and Energy

FROM: Subcommittee Staff

SUBJECT: U.S. Healthcare Workers Victims Of Estimated One
Million Accidental Needlestick Injuries, Annually

A Significant Cause In Spread of Deadly Infectious
Disease Such as AIDS and Hepatitis B Could Be
Mitigated With Use of New -- But Largely Ignored --
Technologies

Additional Federal Worker-Safety Regulation May Be
Required As Needlestick Incidents Grow

INTRODUCTION

At your request, over the last several years, this subcommittee has investigated several issues involving methods for the early detection of HIV and other bloodborne disease. Recently, subcommittee staff has explored the development and possible use of new hardware technologies to protect healthcare workers -- and their patients -- from infectious diseases through accidental needlesticks or sticks from "sharps" used as connective devices in intravenous lines.

These devices account for an estimated one million needlesticks per year, and in millions of dollars in mandated, post-accident testing of healthcare workers for exposure to infectious disease.

Additionally, the healthcare community acknowledges that such injuries result in approximately 12,000 new cases of Hepatitis B infection, annually, and an estimated 40-50 cases of AIDS-HIV, to date, among hospital and clinical workers -- although 40 to 60 percent of all HIV needlesticks go unreported.

Page Two

KEY FINDINGS

-- Staff has found that new syringe and connective device technologies could eliminate as much as 50 percent of these accidental sticks. Fewer workers would get sick if these technologies were incorporated into everyday use.

And healthcare employers would realize an immediate short-term cost savings.

-- But staff has found that hospitals largely are unwilling to adopt these new technologies, citing increased costs for the safer devices.

-- Also, there appears to be little leadership by the appropriate federal agencies to clearly define necessary regulatory standards for protection of healthcare workers. For example, the U.S. Food & Drug Administration has ignored a long-standing petition by healthcare worker unions to launch a comprehensive safety review of devices currently being used, and of more appropriate alternatives.

-- "MedPRO Month" reports that a healthworker's chance of contracting HIV from a single needle prick used on an infected patient is 15 to 30 percent. The direct cost of such accidents (testing) is approximately \$750 million per year.

In essence, healthcare industry employers blame inattentive workers for the epidemic of needlestick injuries, and have been slow to adopt new devices which could save numerous lives and millions of scarce healthcare dollars. Device developers have told the subcommittee that their customers' head-in-the-sand attitude toward safer equipment ironically has kept the cost of that equipment, high, by discouraging competition, innovation and manufacturing economies of scale. And obviously, the higher cost of the new devices compounds the relative low level of utilization of such equipment throughout the healthcare industry.

These developers and manufacturers argue that additional federal safety requirements mandating the use of better devices, and subsequent increases in their use, would (1) bring down prices, (2) dramatically decrease infections among healthcare workers, and (3) save untold millions of dollars by reducing costs for diagnosing and treating infectious disease.

In a letter to subcommittee staff, one manufacturer of safe devices noted that the added cost of outfitting one hospital with safer needles would be about one-twelfth the annualized cost of treating just one AIDS patient.

Page Three

OVERVIEW

Lily, a 40-year-old San Francisco nurse assistant, accidentally pricks her finger with a hypodermic needle hidden under a pile of discarded surgical gauze.

Within a year she tests positive for HIV. Her doctor says there is little doubt that the accidental stick is the cause of her sero-conversion.

Molly, a 59-year-old registered nurse working in a New Jersey hospital, has had three accidental needlesticks between 1983 and 1987. Three months after the third and final stick, she tests positive for HIV.

Doctors say it is impossible to identify which stick results in her infection.

Jane, a Georgia nurse, is infected with hepatitis B when she is accidentally pricked in a doctor's office. As she was pregnant at the time, her baby also contracted the life-threatening disease.

The spread of HIV and hepatitis B virus is a national public health emergency, and the urgency of the problem is no more evident than among health service workers. Healthcare workers are frequently exposed to numerous hazardous devices, devices that they are required to handle and manage under dangerous and difficult circumstances.

Technology exists, but is infrequently used, to eliminate unnecessary needles in hospital regimes, and dramatically reduce viral exposure. The reluctance to incorporate this technology is a major concern within employee ranks.

These problems, and their possible solution, will be the subject of a planned subcommittee hearing early next month, time and place as follows:

Time: 10 a.m.
Date: Friday, February 7, 1992
Place: 2359 Rayburn H.O.B.
Washington, D.C.

Witnesses will include representatives of health service organizations, unions and the device manufacturing sector, as well as federal officials charged with device approval and worker safety regulation.

Five million healthcare professionals in the United States are daily at risk of contracting diseases through the blood and body fluids of infected patients.

Page Four

Surgeons and nurses in the emergency room, phlebotomists in the laboratory, "downstream" individuals such as housekeepers and laundry workers are all put at extreme risk of exposure to life-threatening infectious disease because of the existence and continued use of "naked" needles and other sharp and pointed medical equipment in hospitals and other public health facilities.

-- Each year, 12,000 U.S. healthcare workers contract hepatitis B from accidental needlesticks, and 300 of them die, according to the University of Virginia School of Medicine. The university analysts also say that:

** Healthcare workers have 5 to 15 times greater chance of contracting hepatitis B than the general population.

** The annual number of needlesticks hovers around 1 million, including 16,000 accidental sticks attributed to HIV-contaminated needles.

** More than 75 percent of needlesticks occur after use of the needle, in preparation for disposal, during disposal, or during trash handling. Only 25 percent or fewer occur while the needle is in use.

An estimated 50 percent of needlesticks could be prevented by eliminating unnecessary needles from I.V. lines, and from syringes accessing injection sites.

-- Becton-Dickinson, one of the nation's leading medical device manufacturers, conservatively estimates a potential cost savings of \$87,840 per annum for a single 300 bed hospital. The subcommittee calculates overall annual savings of more than \$40 million for the 500 facilities of this size nationwide.

-- There are more than 6,000 hospitals in the United States. One expert told the subcommittee that the hospital industry in the space of a few years could realize savings of as much as \$600 million from the implementation of safer, protective technology.

It is commonly said that needlestick injuries are caused by the carelessness of healthcare workers or their lack of compliance with universal precautions -- generally, all human blood and certain human body fluids are treated as if known to be infectious for HIV, hepatitis B and other bloodborne pathogens. According to Janine Jagger, a leading researcher and advocate of safer needle technologies, this is a myth:

Page Five

"The issue is not one of user safety but of device safety, and not until the latter is fully implemented will the spiralling number of needlesticks be pared and the risk posed to hospital and healthcare workers decline."

The use of unnecessary needles -- needles not intended for injection purposes, i.e. IV connectors which expose the healthcare worker to an unnecessary risk of a needlestick -- contributes greatly to the transmission of bloodborne pathogens among hospital and healthcare workers. The subcommittee has been told that many such needles can be eliminated altogether or replaced with safer preventive needle technology.

The subcommittee hearing will examine (1) instances of healthcare worker needlestick injuries in hospital and healthcare sites, (2) lack of sufficient administrative management and handling of such injuries on the part of hospitals, (3) cases of unnecessary use of needle-bearing equipment, (4) dangerous gaps in federal oversight of these facilities and workers, and (5) the existence of preventive needle technology designed specifically to make for a safer healthcare workplace environment -- as well as the major roadblocks standing in the way of fully mandating the use of such technology.

NEEDLESTICK INJURIES: HEALTHCARE WORKERS AT RISK

Three years ago, a San Francisco General Hospital nurse accidentally pricked her finger with an AIDS-contaminated needle and contracted the HIV virus. A simple \$1.50 needle guard safety device, like many emerging needle technologies already on the market, could have protected her. Instead, a 3-cent needle wrapped with adhesive tape joined the lines, the standard in most hospitals.

The new device had a hard time gaining acceptance because the hospital considered it "too cumbersome, prohibitively expensive and unworkable."

Clearly, the catcall to "just be safe" does not adequately address the problem, especially given the pressure of a national nursing shortage. Nurses are working perversely longer hours at chronically understaffed hospitals. For example, the nurse cited above, known to the public as Jane Doe, was injured at the end of a 16-hour shift.

In testimony before the Occupational Safety and Health Administration on OSHA's proposed standard for prevention of bloodborne diseases, this worker said:

Page Six

"I have a very strong response to the suggestion that healthcare workers just need to slow down and think -- they just need to prioritize as they work, and then accidents will be less likely to happen. I think that's a myth, it puts the onus and it puts blame on healthcare workers, in a situation where our workload generally increases without supports.

"We can follow rules that are laid down for us but a needle is a needle and accidents happen. We need to be protected from the needles."

It is likely that many cases -- the subcommittee has been told up to as many as 40-60% -- of occupationally acquired HIV go unreported. The reporting of needlesticks to the employer is entirely voluntary, and because of the potentially drastic and devastating professional and personal consequences of HIV exposure, some employees do not report needlestick injuries.

One hospital nurse with more than 20 years work experience was stuck with a hepatitis B contaminated needle while working as part of a 4-person IV catheter team. She told the subcommittee:

"No amount of employee training on how to handle inherently dangerous devices is going to slash the number of needlesticks occurring. I've been managing unsafe devices for over 20 years and I take every precaution there is and I still get stuck. I'll tell you my story, but I refuse to go public. I can't afford to go public. I'll lose my job."

Another healthcare worker, a phlebotomist, who was diagnosed with the AIDS virus after being stuck by a needle while taking blood from a patient is suing a St. Louis medical supplies company for allegedly making dangerous equipment. She feels her life has been turned upside down:

"You constantly wonder, are you going to get sick? How many years have you got? It's like putting a gun to your head and playing Russian roulette."

Needlestick reporting is often a muddled process as one hospital physician told the subcommittee:

"A task juggled among many. Exposed workers don't know where to go to report an injury, and when they do go to report an injury there are 3 or 4 different committees designated to handle the issue. Hospitals don't view it as a serious enough problem and consequently have yet to establish oversight committees to handle the reporting of such injuries."

Page Seven

The typical process an exposed healthcare worker undergoes immediately after experiencing a needlestick and reporting it to hospital personnel is as follows:

(1) Infected worker has blood drawn.

(2) Infected worker is tested for the presence or absence of hepatitis B or HIV (HIV to determine that the worker is negative at the time of the needlestick). This involves testing both the healthcare worker and the source patient.

(3) The healthcare worker is again tested at 6 weeks, 3 months, 6 months and 1 year.

(4) In the case of hepatitis B there may be a vaccination on the spot or if hepatitis B has not yet onset, hepatitis B immune globulin is administered in an attempt to prevent or limit the severity of potential hepatitis B infection.

In the case of HIV, AZT is sometimes offered to prevent infection, though it has not been clinically proven as an accepted effective form of treatment for the disease.

The cost of this general treatment procedure has been estimated to be \$400.

The reduction in hospital expenses associated with post injury testing would greatly exceed the cost of implementing protective devices.

Physicians' professional organizations, such as the American Medical Association, have been relatively quiet concerning this issue. One healthcare workers union representative surmised that physician groups are simply "not talking about this issue," because of the perceived added cost.

However, the Service Employees International Union, the National Phlebotomy Association, the American Nurses Association and the Federation of Nurses and Health Professionals are among a number of non-physician, professional groups pressing for better devices and stricter safety standards.

Page Eight

FEDERAL SAFETY STANDARDS: TOO LITTLE? TOO LATE?

The Occupational Safety and Health Administration (OSHA) recently released a new set of standards to provide for a safer work environment for healthcare workers. The standards require employers to provide workers with additional training, protective clothing, and puncture-proof receptacles for contaminated needles and other medical wastes, as well as, in the case of hepatitis, vaccination against the virus.

The OSHA guidelines include a provision requiring healthcare and hospital facilities to use engineering controls to eliminate or minimize employee exposure.

However, there is some question as to whether these guidelines will get at the real problem of significantly cutting down the incidence of needlesticks among healthcare professionals, or lead to the implementation of safer needle technologies.

One leading health professional said, "It's a start, but that's about it."

OSHA estimates the annual cost of the new regulations at \$821 million for all affected industries. The largest annual costs for personal protective equipment -- such as gloves -- is gauged at about \$334 million.

The Federal Centers for Disease Control (CDC) has taken what one source has dubbed a "shamefully backward approach to a rapidly growing public health epidemic. There has been little advanced leadership and the result has been a bandwagon effect."

In 1983, the CDC issued Universal Precaution Guidelines to curtail healthcare workers' risk of exposure to infectious diseases, such as AIDS and hepatitis B. Unfortunately, these standards have been little more than a "keeping the hands clean" measure rather than a hard-hitting substantive approach to ameliorating a major public health problem.

The CDC guidelines stack the deck heavily against the healthcare worker. The burden is placed unfairly on the healthcare worker to protect themselves from needlestick injuries. Healthcare workers are essentially "guilty even when proven innocent," said a federal regulatory official who requested anonymity.

However, Jagger states, "the solution does not lie in making the users more careful, but in making the devices safer."

Page Nine

The U.S. Food and Drug Administration has done little more than sit on the sidelines as the issue has unraveled before their very eyes. Last April, the Service Employees International Union (SEIU), which represents close to 400,000 healthcare workers across the country, submitted a lengthy petition to the FDA to ensure that needle-bearing devices are safe and effective. Specifically, the petition requested regulatory action to promulgate performance standards for needle-bearing devices that pierce the skin.

The FDA did not respond to the petition.

STATES ACT IN ABSENCE OF FEDS

While federal health agencies have remained relatively quiet on the issue of needlestick safety, some states -- recognizing an emerging health problem -- have begun to promulgate new restrictions and standards on their own.

New York is the first and only state to get cracking on the issue of safer needle technologies in hospitals and the evaluation of the incidence of needlestick injuries. In May 1990, the state passed a law requiring pilot testing of devices designed to prevent needlesticks.

The study looked at a geographical and institutional-size cross-section of 10 hospitals and addressed (1) the impact of the technology on incidence of injury and disease transmission, (2) availability of the technology, (3) the cost of implementing a safer technology when compared to savings realized from reducing exposures and disease transmission, (4) the practicality of the technology and willingness of workers to use safer devices, and (5) recommendations regarding continued use.

The project concluded on December 31, 1991 and data is currently being analyzed. State health department officials told the subcommittee that preliminary findings would be available for testimony at the hearing.

Also to be available at the subcommittee hearing are results of the first statewide survey to determine the number of needlesticks occurring in New York hospitals. One health department official told the subcommittee that the results are "staggering."

Page Ten

SMALL AND LARGE MANUFACTURERS -- ONE BIG LOGJAM

The FDA is the only federal agency with the authority to regulate needle-bearing devices but, because it has failed to do so, small and large manufacturers are left scrambling to identify opportunities enter the marketplace and are generally hesitant to head into this foggy area.

The lack of federal initiative and leadership in issuing minimum device standards to evaluate the safety and efficacy of needle-bearing devices has forced manufacturers to rely instead on private product liability insurance agencies to carry out risk-management reviews. The cost of this private risk assessment then must be added to the development and marketing cost for the product.

Manufacturers are left to fend for themselves. In the words of one small manufacturer who requested anonymity, the situation amounts to a "heap of regulatory confusion."

Another, David A. Low, president of Sherwood Medical, of St. Louis, Mo., said the "most significant delay has occurred due to lack of a cohesive, structured and detailed regulatory program emanating either from OSHA or CDC.

"Many hospitals," Low said, "have employed a wait-and-see attitude relative to the mandates that they will be required to comply with in the future...healthcare institutions have been hesitant to make a firm commitment until such time as they could receive a clear direction from the various governmental agencies."

Several manufacturers told the subcommittee that hospitals also are rejecting their products on the grounds that they are more costly than conventional needle-based products. Clearly, though, as market volume increases, prices are driven down and a viable and competitive market emerges.

Hospitals across the board have taken the view that the chance of an accidental needlestick by a healthcare worker appears to be very slight if the system of universal precautions is used. Thus, the introduction of a safer needle device is not warranted.

Even when product evaluations turn out positive, hospital purchasing departments have been slow to order because of added costs.

Page Eleven

Some examples of the cost differentials:

-- In a recent open bid to sell a simple, standard syringe, the buyers for a major hospital group turned down the new, anti-stick hypo for an old-technology device on the basis of a five cents per syringe cost difference.

According to the new device manufacturer, International Medication Systems, Ltd., the buyer said "we will not pay one penny more for your safety," an innovation which virtually would have eliminated accidental sticks during injection.

-- The Pascal Medical Corporation markets a safer, IV catheter syringe at an estimated \$60 annual cost differential in comparison with standard, less-safe technology. The cost increase at a typical hospital might amount to \$13,000 per year -- or about one-twelfth the maintenance costs of just one AIDS patient.

William Tarello, Vice-President of Operations for the company, told the subcommittee that "The medical device market has to be one of the toughest markets to be involved in." And further, that "if faced with the decision to spend a few more cents and prevent a fatal needlestick, the hospital will go for the immediate cost savings."

Referring to the FDA device review process, he said: "Beside(s) the market penetration (obstacle), a company is faced with federal regulation which will be more demanding and in many ways needlessly more complicated in the next couple couple years."

-- In a higher-cost category, North American Medical Products sells a multi-purpose, anti-accident syringe for a dime more than its traditional, and less safe, competitive product. And they have had some success.

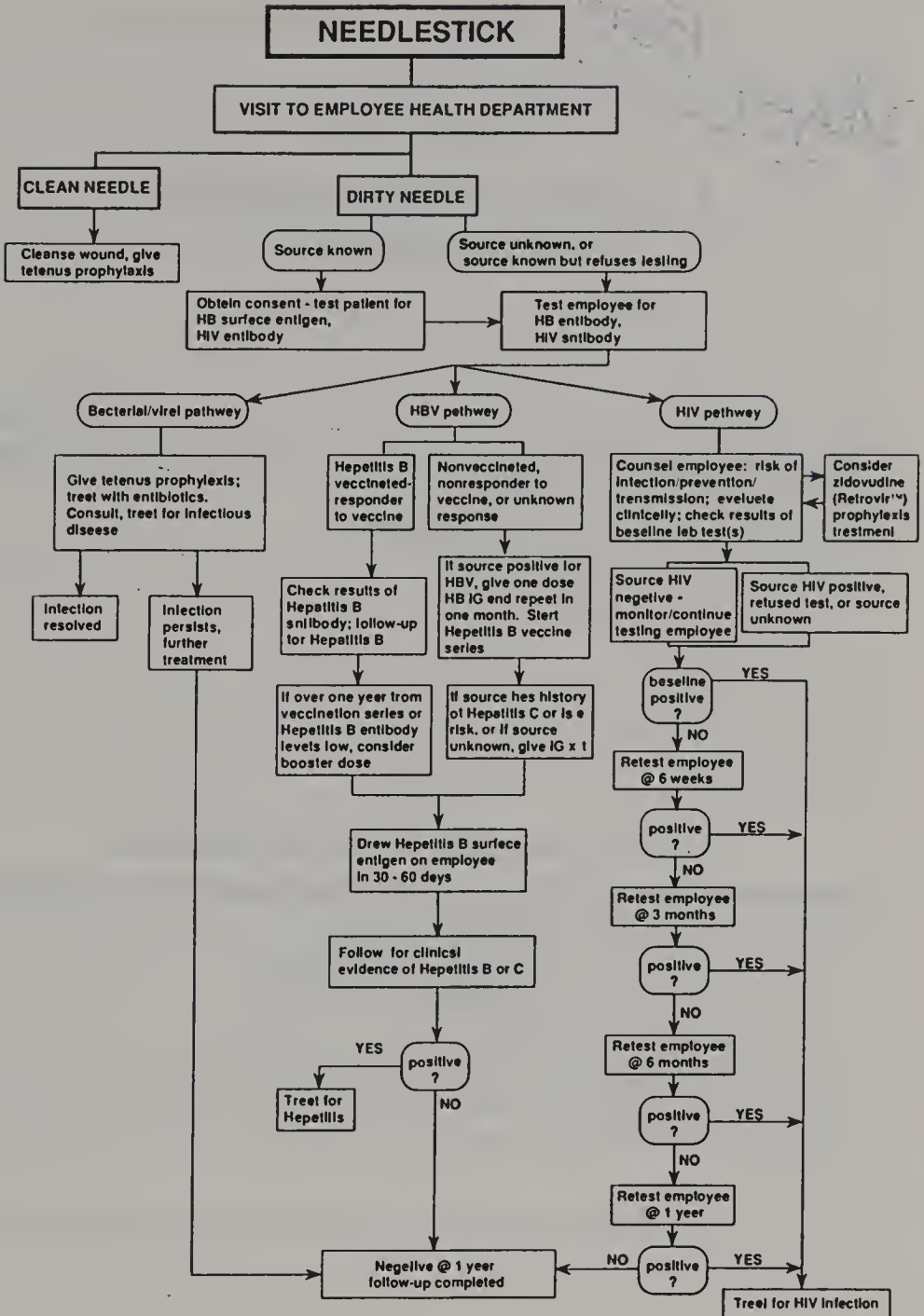
"Since our prices are the most competitive in the industry (among anti-accident manufacturers), we have been well-received on this issue," said Art Gianokos, company president.

Incorporation of new devices mean a change of habits, procedures and protocols of many hospital departments and this often translates into significant time delays even before the hospital's financial approval or disapproval is considered.

Page Twelve

But regardless of these obstacles -- some substantive, others not -- the cost of treating accidentally stuck healthcare workers, higher insurance premiums and potential law suits is significantly higher than the implementation of protective devices.

The subcommittee has been told that in some instances, technological research and development has been slowed because of backbiting competitiveness on the part of some larger manufacturers. These bigger companies buy up the patents to medical devices from smaller manufacturers and inventors and then sit on the product, retarding further advancement and development of the product and the possibility of its sale to hospitals and other healthcare facilities.



Peggy Ferro

Testimony of

"Jean Roe"

Certified Nursing Assistant
San Francisco, CA

Healthcare Worker Safety and Needlestick Injuries

to the
House Committee on Small Business
Subcommittee on Regulation, Business Opportunities,
and Energy
February 7, 1992

Good morning, Congressman Wyden and members of the Committee.

I am honored to be here today to tell you about a hazard that I and other healthcare workers face every day we go to work -- the danger of needlestick injuries caused by unprotected, exposed needles.

Regrettably, I cannot face you in person because I must protect my confidentiality, both to preserve my privacy and protect myself from discrimination.

I cannot give you my legal name, but I am known by the pseudonym, "Jean Roe."

I am a healthcare worker and a member of SEIU Local 250. I have been a Certified Nursing Assistant since 1969. I work at a major private hospital in San Francisco, California. It was in this hospital, in the winter of 1990, that I was stuck by an unprotected needle that was contaminated with HIV-infected blood. I continue to work at this hospital today.

I am a female healthcare worker who is now HIV infected from a needlestick injury -- a documented occupational transmission. If my HIV disease progresses and I acquire full-blown AIDS then the Centers for Disease Control (CDC) will classify me in their HIV/AIDS Surveillance Report under a category called "Other/Undetermined".

I am not an "Other." I am "Jean Roe," and I am here today to tell my story. I am here to testify in favor of safer working conditions in healthcare facilities nationwide, so that workers will no longer dread needlestick injuries and the possibility of becoming HIV positive. I believe, as do growing numbers of other healthcare workers, that these injuries and sero-conversions can be prevented. Prevention can happen only if there is a resolve by government to move against the healthcare industry's negligence.

I speak from experience. I have volunteered hundreds of hours of my time to educate and train healthcare workers on prevention of HIV and hepatitis B (HBV) transmission in the workplace. Throughout the 1980's, I was active in my local union's AIDS education activities. I have helped produce some of the first materials on AIDS for healthcare workers. Early on in the AIDS epidemic, I strongly advocated for HIV inpatient services to be provided at my hospital, which resulted in the implementation of a dedicated AIDS unit. I testified on behalf of a strong OSHA bloodborne disease standard, which we finally won in December, 1991 after a five year-long fight. I have pressed my hospital and other San Francisco Bay Area hospitals for better infection control and improved medical treatment and services for the HIV-positive population.

My needlestick injury occurred when I was cleaning up the bedside table of a patient

under my care. The patient was newly admitted to my unit and was medically unstable. My first priority was my patient's medical status -- stabilizing his condition and keeping him alive. That night, I was also responsible for two other patients, one of whom was also medically unstable. I was trying to cope with a very heavy patient care load.

During my shift, an intern drew blood from one of the patients and had to use two needles to get a proper specimen. One of the needles was left improperly by the intern on the bedside table. It was hidden from view by gauze. As I cleaned up the bedside table, the contaminated needle punctured my finger. I could not imagine a contaminated needle lay hidden from my view. Hidden or not, it was there. I didn't see it. I couldn't anticipate it. While I was doing my compassionate, professional best to care for my patients that night, I was exposed to an unprotected needle with enough HIV-contaminated blood to infect me.

I could not immediately report my injury. Staffing was so poor that there was no one to take my place. I could not leave my floor to report my injury to the Emergency Room. Instead I had to call Employee Health Services the next day. After explaining what had happened to me, I was told to come in at the end of the day. This delayed response by Employee Health Services was a violation of accepted exposure management protocol because I needed to be seen immediately if I was to choose to use AZT as a prophylaxis. Furthermore, I was not given adequate counseling. I was told that my exposure was "high-risk," but not to worry.

I became HIV positive several weeks later. I was called into the occupational medicine office and given the news of test results in person. This began my difficult struggle to manage my injury and infection, keep my income, and maintain my dignity. I have lived a nightmare ever since.

I developed side effects from the AZT. I was re-exposed to tuberculosis before I could be transferred out of the unit. I had to take an anti-TB prophylactic medication and developed peripheral neuropathy -- painful cramps in my legs. I took an anti-inflammatory medication to reduce swelling in my elbows caused by HIV-related arthritis. I then developed a life-threatening perforated ulcer and spent two weeks in the hospital.

My problems are not confined to medical ones. The hospital has attempted to discipline me for using my sick time. My confidentiality is constantly at risk. This nightmare does not affect me alone; it includes every healthcare worker who is exposed to unsafe needles. Every needlestick injury is a serious event whether or not it results in HIV-infection or HBV infection is a serious event.

Let me give you a dose of reality about being a healthcare worker. You are told by management to "be more careful," "work slower," and "act safely," This is meaningless when you are working 12 to 16 hour shifts, carrying double patient loads, and facing a shortage of trained staff. That sums up the "prevention program" at my facility and at many other hospitals around the country.

The technology was available in 1990 to prevent my needlestick injury. At that time, my hospital did not use safer needle-bearing devices.

Since my injury, I have urged facility committees and management personnel responsible for safety at my hospital to evaluate, pilot and purchase safer needle-bearing devices. These devices must be supplied to everyone -- hospital-wide -- just as gloves and the hepatitis B vaccine are made readily accessible. To add insult to injury, management refused my membership on the hospital's needlestick prevention committee.

I believe that all hospitals and medical facilities should be required to use safer medical devices such as ones that eliminate needles altogether, like needle-less systems to connect I.V. lines and access injection ports or devices that feature a barrier between the needle and our hands, such as a shield, sheath, cannula, or rod.

Unsafe medical devices must be taken off the market and medical facilities instructed to choose the best available technology on the market. There are many safer devices now that could prevent needlestick injuries. My hospital, and most other hospitals, have been reluctant to adopt safer needle-bearing devices to protect healthcare workers. I am convinced that they will not act on their own despite what has happened to me -- and other healthcare workers. I am not the only healthcare worker to become HIV-infected after an occupational exposure at my hospital.

Universal precautions must become something more than rhetoric. Universal precautions must be expanded beyond the provision of gloves, gown, masks, and sharps containers to include safer needle-bearing devices. To protect healthcare workers against infection, we must protect them from dangerous instruments.

Congressman Wyden, you and the other members of the Subcommittee can play an important role in the campaign to clean up the workplace and protect workers from unsafe, dangerous needles. Healthcare workers desperately need safer medical devices, and regulations that require their use.

It's too late for these devices to save me now, but they will save people I cherish --

healthcare workers who cherish me and cherish you. Everyone needs protection from bloodborne infectious diseases. Please don't wait for the list of "others" to grow, and grow, before effective regulatory action is taken. To borrow a quote from "Jane Doe," my friend and a healthcare worker at another hospital in San Francisco who became HIV positive from a needlestick injury in 1987: "We need to be protected from the needles."

In closing, Members of the Committee, I'd like you to remember these names -- Jane Doe, Pat Doe, Melissa C, Ron L. -- all healthcare workers who are now HIV-infected after an occupational exposure. Their injuries could have been prevented. We must take immediate action to prevent further needlestick injuries.

Thank you.

Testimony of

Janet Christensen
Registered Nurse
San Francisco, CA

Healthcare Worker Safety and Needlestick
Injuries

to the
House Committee on Small Business
Subcommittee on Regulation, Business Opportunities,
and Energy
February 7, 1992

Good morning. My name is Janet Christensen. I work at a major public hospital in San Francisco and am a member of SEIU Local 790. I have been a registered nurse since 1970. I am grateful for this opportunity to share my story with this Subcommittee.

On March 29, 1991, I was assigned to work in the pre-op holding room at a major public hospital in San Francisco. This is a work area staffed by the Ambulatory Surgical Center. On a normal day, I can start anywhere from 5 to 15 I.V.'s on inpatients and outpatients before they enter the operating room. A standard angiocath is stocked. A variety of sizes are available, but the 18 Gauge is the most commonly utilized.

The morning of the needlestick injury, I was working my way through the accumulated cases waiting to enter the operating room. The Anesthesia Attending Resident and a medical student came to the bedside of a patient I was working with. They were interviewing the patient for surgery as I was attempting to start an I.V. I was having some difficulty with the insertion so the medical student stepped over to assist me. I finally got into the vein and he handed me the I.V. tubing. As I was withdrawing the needle from the sheath which was in place in the patient's vein, the medical student's free hand swung back and hit the contaminated stylet on the fleshy, palm side of his hand. The needle penetrated deeply into his hand.

We both knew that his type of exposure was extremely high risk: a large bore hollow needle, full of blood, stuck deeply into a highly vascular area. We also knew that the patient was at high risk to be HIV-positive because he had been recently released from prison, and had a history of IV drug abuse. The patient said that he had tested negative in the past. There was great relief on both the medical student's and my part. We followed the hospital protocol for a needlestick injury. We obtained consent to test the patient's blood, although we had to wait for consent because he had been premedicated with narcotics. The medical student called the post-exposure hot line at our hospital and started the process to be entered into the protocol. He elected to start an immediate regimen of AZT because it was a Friday and the patient's HIV-test results would not be available until after the weekend.

On Monday, the results came back HIV positive. By that time the medical student was already experiencing clinical signs of adverse reaction to the AZT. This reaction coupled with the terrible news that the patient had not been correct about his HIV status was a depressing blow for him. I felt extreme empathy and guilt when he told me the results. I was so sorry for what had occurred and kept replaying the incident in my head to see what had gone wrong. As time went on, the medical student's reaction to the AZT drug became so overwhelming he had to withdraw from his clinical duties.

In May, a colleague that had previously worked in the Emergency Room, showed me a self covering Critikon angiocath. In the Emergency Room it was standard issue. As I looked

at the device I realized that the medical student's needlestick injury need never have occurred. If I had used this angiocath the student would have hit the plastic barrier that covers the contaminated needle instead of the needle that penetrated his skin. I also realized that this needle might well have prevented a needlestick to a co-worker that happened in the same area one month prior to the incident I just described.

I called the Administrator of Central Supply and requested that we be given a stock of these safer needles. I was told that a committee headed by the Chief of Employee Health Services had decided the protected/safer needle would only be stocked in the Emergency Room and ambulance areas, because they have limited access to red boxes (sharps containers).

I then embarked on an incredible odyssey into the maze of hospital bureaucracy. I filed a grievance with the help of my union in June 1991, to demand safer needles for the entire hospital, not just selected areas, such as the Emergency Room. The grievance was settled in my favor by Mr. R. Cordova, the Hospital Administrator in November 1991. We still do not have the devices in place nor do we have a plan in place to do so, but slowly the committee that was formed to oversee this and other aspects of bloodborne contaminants in the workplace, is working its way towards that goal.

I am working at an institution that has been a leader in research relating to HIV infection and in instituting a model post exposure protocol for workers. The lack of organization and insensitivity I experienced gaining access to a safer medical device and establishing a hospital based committee to reduce exposure, can only, I imagine, be magnified in hospitals and healthcare facilities where they feel an "AIDS Problem" does not exist.

The assumption that the implementation of universal precautions is enough to protect healthcare workers from bloodborne contamination is incorrect. Universal precautions are necessary, but do not go far enough. There has been an associated inference that if you follow universal precautions you are safe, and that if you suffer exposure, you were somehow careless and are partially or wholly at fault.

My experience has led me to the following conclusions:

1. Looking back, I realize that I was totally unaware as a nurse that there were devices on the market that protected the healthcare worker. The focus from a nursing perspective has always been on preventing injury and contamination to the patient. Once I knew there were products available my ability to access information was difficult and limited. There is a need for education as to what is available.

2. Compounding the problem is the fact that the people responsible for creating a safer environment for me to work in haven't got a clue about that work and what would make it safer. The majority of the people making decisions are administrative people without clinical experience, or no recent clinical experience. A greater degree of involvement of those at risk in the decision process is necessary.
3. The number of studies/research protocols investigating methods to prevent needlestick nationwide is a fraction of the number for post-exposure studies. The studies emphasis has been focused on what to do after the injury occurs. Money needs to be allocated to prevention research.
4. It is unclear which, if any, of the "safer" medical devices are truly effective or really are safer since no standardized testing is going on. Standardization and minimal requirements must be established.
5. The OSHA regulations are not clear when it comes to introduction of engineering controls in the workplace to improve safety. Critical definitions of what is safer have been left out.
6. It would be useful if nationwide trials of devices could be implemented and data compiled accumulatively on the testing so that hospitals would have some information to guide in decision making.
7. It is also necessary for some standard of quality to be enacted to assure that the products perform consistently at the level of safety they are supposed to.

It is absolutely mandatory that federal minimal standards for protection of healthcare workers be enacted. Two requirements are needed. We must demand of the industry that they produce high quality products that truly are safer, and demanding that hospitals use these products to protect workers.

Healthcare workers are caring for HIV-infected people who are entering the system at early phases in the disease process and, with the introduction of new drugs and better treatment, are living longer. If healthcare workers cannot feel safe at work they become less productive and wonder whether the job is worth risking their lives. If a combination of education and introduction of safer working conditions can lower the risk of exposure, then every effort must be taken to ensure that this occurs.

Thank you.

Attachments for Testimony of Janet Christensen

February 7, 1992

JANET CHRISTENSEN
2485 SKYPARK DRIVE
HILLSBOROUGH, CALIFORNIA 94010
415 579 1444

Born:
1948 Pensacola, Florida

Education:
1970 B.S.N., Brigham Young University.
1977 B.S. in Psychology, University of Utah.

Work Experience

1984-present: Per Diem at S.F.G.H. Work experience at S.F.G.H. includes the Surgical I.C.U., the Nursery, Recovery Room and Ambulatory Surgery

1978-1984: Research Associate for the University of California, SF. Primary area of concern was Cardiovascular/Pulmonary impairment in the acute care setting. I was responsible for maintaining & supervising a animal lab, and obtaining and compiling data on patients in clinical studies. Supervisor: Frank Lewis M.D.

1974-1978 Worked as staff nurse in the Intermountain Respiratory I.C.U. in Salt Lake City. I was a member of the air transport unit that brought acutely ill patients from outlying area for care.

1972-1974 Staff Nurse at the University of California, S.F. in the Surgical I.C.U.

1970-1972 Staff Nurse at Stanford University Hospital on Medical Surgical Ward

Publications:

Miller SW, Christensen JM. Long-term and environmental effects of medial septal lesions in rats. Physiological Psychology, 8(3):330-336, 1980

Pitte LH, Lewis FR, Christensen JM, Katkis J. Pulmonary edema and head injury. Presented at the annual meeting of the American Association of Neurological Surgeons, New York, New York, April 1980.

JANET CHRISTENSEN

Tranbaugh RF, Lewis FR, Christensen JM, Elings VB. Pulmonary effects of massive crytalloid infusion and lowered colloid osmotic pressure. Chest 1981

Lewis FR, Christensen JM, Elings VB. The effect of PEEP on non-cardiogenic pulmonary edema. Presented at the 3rd World Congress for Critical Care Medicine, Washington D. U., May 1981. Journal of Society of Critical Care Medicine 9(3):258, 1981

Tranbaugh RF, Elings VB, Christensen JM, Lewis FR. Determinants of pulmonary interstitial fluid accumulation after trauma. Presented at the annual meeting of the American Association for the Surgery of Trauma, Hot Springs, Virginia, Sept., 1981. Journal of Trauma, 1981

Tranbaugh RF, Elings VB, Christensen JM, Lewis FR. Effects of inhalation injury on lung water accumulation. Presented at the annual American Burn Association meeting in New Orleans, Louisiana, March, 1981.

Tranbaugh RF, Lewis FR, Christensen JM, Elings VB. Lung water changes after thermal injury: the effects of crytalloid resuscitation and sepsis. Annals of Surgery 192:479-490, 1980.

Mackersie RC, Christensen JC, Pitts L. and Lewis FR. Pulmonary extravascular fluid accumulation following intracranial Injury. J. of Trauma 23: 968-975, 1983.

Mackersie RC, Christensen JM and Lewis FR. The prehospital use of external counterpressure: Does MAST make a difference? J. of Trauma, 1984

Lewis FR, Tranbaugh RF, Christensen J and Elings VB. Determinations of lung water after major trauma. In Organversagen Wahrend Der Intensivtherapie, Ed. K Peter, George Thieme Verlag, Stuttgart, 1984

Ostrow LB, Christensen JM and Lewis FR. The acute hemodynamic effects of pulmonary microembolization. Surgery, 1984.

SERVICE EMPLOYEES

INTERNATIONAL UNION. AFL-CIO. CLC

WESTERN STATES REGION
240 GOLDEN GATE AVE. •

(415) 474-2603
SAN FRANCISCO, CA 94102



JOHN J. SWEENEY
INTERNATIONAL PRESIDENT

RICHARD W. CORDTZ
INTERNATIONAL SECRETARY-TREASURER

P R E S S R E L E A S E

FOR IMMEDIATE RELEASE
DECEMBER 6, 1991, San Francisco, CA

SAFER MEDICAL DEVICE MADE AVAILABLE HOSPITAL-WIDE AT SAN FRANCISCO GENERAL HOSPITAL

In response to a health and safety grievance filed on October 2, 1991 by Service Employees International Union locals:

Local 250 Hospital and Healthcare Workers Union,
Local 790 United Public Employees, and
Local 8000 San Francisco Interns and Residents Association

at San Francisco General Hospital, the director of the hospital, Richard Cordova, in a meeting with the unions today, agreed to the following:

(1) The Critikon Protektiv I.V. catheter will be available throughout the hospital. It will be phased in over 6-9 months.

(2) The Critikon will be introduced into areas as training is completed in that area.

(3) The plan for the implementation of the training program will be the first charge of the newly-formed San Francisco General Hospital Needlestick Prevention Committee.

The unions expressed satisfaction with the decision, and stated that "implementing safer medical devices hospital-wide will reduce the number of needlestick injuries at San Francisco General Hospital, and make the workplace physically safer for hospital workers, patients, and visitors."

"There is an epidemic of needlestick injuries in this country which must be addressed by all medical institutions. San Francisco General Hospital is well-positioned to be a leader in the effort to control and prevent these injuries. The successful resolution of the Critikon grievance is an important step in that direction," the unions concluded.

The grievance was filed after the hospital refused repeated union and employee requests to distribute hospital-wide a safer

medical device, the Critikon Protectiv I.V. catheter, to prevent needlestick injuries. The Critikon Protektiv I.V. catheter has a protective shield that slides over the contaminated needle after it is withdrawn from the vein. San Francisco General Hospital currently distributes this safer device only to emergency room and emergency medical service employees.

On March 29, 1991 a hospital nurse in the pre-operating room area accidentally injured a medical student with a contaminated needle which contained HIV positive blood. The nurse, Janet Christensen, and the unions contend that the needlestick injury could have been prevented if Christensen had used the Critikon safer medical device. The hospital, however, does not allow her department to use this device.

In the November 15 grievance meeting with director Cordova, the unions pointed out that San Francisco General Hospital does not have a needlestick injury prevention program which would systematically evaluate and incorporate safer medical devices to prevent needlestick injuries. Instead, the hospital is widely known for its needlestick injury management protocol, which the unions contend should not be the only response of the hospital to needlestick injuries which may transmit HIV/AIDS or hepatitis B.

The union had requested San Francisco General Hospital set up a hospital-wide committee to implement a needlestick injury prevention program.

#

PRESS RELEASE CONTACTS:

The Grievant: Janet Christensen, R.N., (w) 821-8133 (10-6p.m. weekdays); (h) 579-1444 evenings.

Local 790 chief shop steward: Lorraine Thiebaud, R.N., (h) (510) 548-1380, (w) (415) 821-8128.

Representing San Francisco Interns and Residents Association: Dr. Peter Lurie, (w) (415) 597-9138; (h) (415) 647-5428.

Local 790 business agent: Susan Rosenthal, (w) (415) 673-8755.

Local 250 business agent: Paul Roose, (w) (415) 441-2500.

SEIU Health and Safety Department: John Mehring, (415) 474-2603, or (206) 448-7348.

ENCLOSURES:

(1) October 2, 1991 Grievance, including Janet Christensen's testimony.

- (2) Dr. Peter Lurie's Statement at November 15 Grievance meeting.
- (3) Dr. Janine Jagger, University of Virginia, November 13, 1991 letter to Linda Chiarello, New York State Department of Health regarding Critikon Protektiv I.V. Catheter.
- (4) Gail Douglas, R.N., M.P.H., Boston University School of Public Health, November 18, 1991 letter to Richard Cordova.
- (5) Newspaper articles.
- (6) Critikon brochure.

Northern California Joint Council of Service Employees No. 2

Service Employees International Union
the largest AFL-CIO Union in California



Paul M. Varacalli, President

Kerry Newkirk, Secretary-Treasurer

Theatre & Amusement Janitors
Local 9, San Francisco

October 2, 1991

Service Employees
Local 14, San Francisco

Service Employees International
Local 18, Oakland

Window Cleaners
Local 44, San Francisco

Service Employees
Local 77, San Jose

Building Service Employees
Local 97, San Francisco

Theatrical Janitor's Union
Local 121, Oakland

Hospital & Institutional Workers
Local 250, Northern California

Cemetery Workers & Greens Attendants
Local 265, San Francisco & East Bay

Port-Museum Employees Guild
Local 280, Northern California

United Public Employees
Local 790, San Francisco & East Bay

Social Services
Local 835, Northern California

Nepo Association of Public Employees
Local 814, Nepo

United Service Employees
Local 816, Oakland

United Staircase Employees
Local 880, Staircase

Sanoma County Organization of
Public Employees Local 707, Santa Rosa

Service Employees International
Local 715, San Jose

Martin Association of Public Employees
Local 949, San Rafael

California Faculty Association
Local 1000

BART Police Officers
Local 1008, Oakland

Richard Cordova
Executive Director
San Francisco General Hospital
1001 Potrero Avenue
San Francisco, CA 94110

Dear Mr. Cordova:

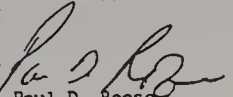
On behalf of the SEIU Joint Council, I submit two grievances, one under each of the MOU's.

In accordance with Section D of the grievance procedure, we are requesting a mutual waiver of the lower steps of the grievance procedure. This request is based on the nature of the grievance, a hospital-wide issue.

Susan Rosenthal and I would be happy to meet with you and/or your design at a convenient time to discuss these grievances.

Also, enclosed is a request for information related to these grievances.

Sincerely,


Paul D. Roose
Field Representative

PDR/rp

L1108B49.psf
ope 3 afl-cio(12)

hcc: Sandy Reshes, Hospital Division Director
Susan Rosenthal, Local 790
Dale Butler, SEIU 8000
John Mehring, SEIU West Region
T. Gatan

240 Golden Gate Ave., San Francisco, CA 94102, (415) 673-8755, (415) 465-0120

DATE	
SEIU INITIALS	MGT INITIALS

PLEASE TYPE OR PRINT IN BALLPOINT (PRESS FIRMLY)

Hospital and Healthcare Workers Union

STANDARD GRIEVANCE FORM

DATE	GRIEV NO
10-1-91	GH-01191C

TO: SUPERVISOR (NAME & TITLE)		INSTALLATION		PHONE—OFFICE	
RICHARD CORONA, EXEC. DIRECTOR		San Francisco General Hospital		415 821-8100	
FROM: SEIU Local 250		BUSINESS ADDRESS			
		240 Golden Gate Ave. San Francisco, CA 94102			
STEP 2 AUTHORIZED UNION REP				PHONE—OFFICE	
Paul D. Roose, Field Representative				(415) 441-2500	
STEP 1 MEETING: HELD ON (DATE/TIME)		BETWEEN MGT REPRESENTATIVE		AND GRIEVANT	
				STEWART	
GRIEVANT'S NAME (OR CLASS)					PHONE
AN REPRESENTED CLASSES					
HOME ADDRESS		CITY	STATE	ZIP	
JOB CLASSIFICATION		SFGH SENIORITY DATE	DEPT SENIORITY DATE	DUTY HOURS	
Department					
		SOCIAL SECURITY NO		Civil Service	
				YES NO	
OFF DAYS		SA	SU	M	T
ROTATING		W	TH	F	
FIXED—CHECK AS APPLICABLE					
STEP 1: RENDERED ON (DATE/TIME)		BY (NAME & TITLE)		SUPERVISOR'S INITIALS (UPON REQUEST)	
DECISION					

PURSUANT TO Appendix A of the MOU

WE HEREBY APPEAL TO STEP 2. THE FOLLOWING GRIEVANCE

VIOLATION: INCLUDING BUT NOT LIMITED TO SEIU/City MOU Section 30 A DPH MOU, ART. & SECT. 25A1, 25D
 OTHER GROUNDS: COMPLIANCE ASSISTANCE GUIDELINE FOR THE 2-27-90 OSHA INSTRUCTION
 CCL 2-2.446 ENFORCEMENT PROCEDURES FOR OCCUPATIONAL EXPOSURE TO HEPATITIS B
 VIRUS AND HUMAN IMMUNODEFICIENCY VIRUS — US DoI, OSHA 1991

FACTS: WHAT HAPPENED

SEE ATTACHED

☐ ADDITIONAL SHEET ATTACH

UNION CONTENTIONS: REASONS FOR GRIEVANCE

SEE ATTACHED

☐ ADDITIONAL SHEET ATTACH

CORRECTIVE ACTION REQUESTED: IMMEDIATELY DISTRIBUTE THE CRITICISM DEVICE
 THROUGHOUT SFGH. CONDUCT ALL NECESSARY IN-SERVICE
 TRAINING OF EMPLOYEES AT THE TIME OF ITS INTRODUCTION.

Field Rep./ DESIGNEE Paul D. Roose

SIGNATURE ▶ Paul D. Roose

ORIGINAL TO Immediate Supervisor

Facts:

During 1991, the hospital began using the PROTECT IV Catheter, made by Critikon, in the Emergency Room and for Emergency Services. This is a self-sheathing needle designed to prevent needlesticks. Individual employee requests to use this device in other departments have been turned down.

By letter to Hospital Director Cordova in July 1991, SEIU Field Representative Susan Rosenthal (Local 790) requested hospital-wide usage of this device. To date, this request has not been complied with.

In February 1991, a serious needlestick injury occurred in the pre-op room. RN Janet Christensen was holding an exposed IV Catheter needle and a UC Davis medical student stuck himself on the needle. The blood in the needle was later found to be HIV-positive.

Union Contentions:

The union contends that SFGH is in violation of the above-cited provisions. In applying the general language of providing safe working conditions, the hospital must follow current OSHA guidelines. In this case, the guidelines for controlling and preventing employee exposure to bloodborne pathogens require that "engineering controls should be used in preference to other control methods." (See Page 5 of OSHA Guideline).

Examples of controls include "self-sheathing needles."

The union also contends that the hospital has introduced the Critikon device in certain areas of the hospital because it believes it is a safer device. To prevent its use in all areas of the hospital now constitutes willful neglect of the health and safety of all exposed employees.

The union further contends that the incident of February 1991 could have been prevented had the Critikon device been used.

TESTIMONY OF JANET CHRISTENSEN, R.N.
San Francisco General Hospital
JULY 19, 1991

On March 29, 1991 I was assigned to work in the pre-op holding room at San Francisco General Hospital. This area requires the nurse working there to start 5 to 15 I.V.s per 8 hour day. The angiocath stocked is a Deseret. An 18g is the most commonly used size.

I was working with a same day surgery patient getting him ready for the O.R. The anesthesia attending resident and a medical student came to the patient's bedside to interview the patient as I was attempting to start an I.V.

I was having some difficulty with the insertion so the medical student stepped over to assist me. I finally got into the vein and he handed me the I.V. tubing. As I was withdrawing the needle, the medical student's other hand swung back and hit the contaminated angiocath stylet needle on the fleshy, palm side of his hand. The needle penetrated into his hand.

We followed protocol for a needlestick injury. We obtained consent to test the patient's blood and the results came back HIV positive.

In May a nurse that works in the surgery center brought back a self-covering Critikon angiocath from the E.R. As I looked at the device I realized that the medical student's needlestick injury need never have occurred. If I had this angiocath the medical student would have hit the plastic barrier with his hand, instead of a sharp contaminated needle that penetrated his skin.

I called Deana Mooney in CPD and requested that we be given a stock of these safer needles. I was told that a needlestick committee headed by Lee Wugofski, M.D. had decided the protected needle would only be stocked in the E.R. and ambulance areas, "because they have limited access to red boxes[sharps containers]."

REQUEST FOR INFORMATION
NECESSARY FOR PROCESSING A GRIEVANCE

In accordance with Section 6 of the Memorandum of Understanding between the SEIU and the DEPARTMENT OF PUBLIC HEALTH, SEIU LOCAL 250 makes the following request(s):

Name of Grievant (or class) ALL REPRESENTED CLASSES
 Issue CRITIKON IV CATHETER DEVICE
 Grievance No. GH-001-91C Date of Request 10-2-91
 Shop Steward Making Request PAUL ROGSE

INTERVIEWS:

<u>Name of Person to be Interviewed</u>	<u>Estimated Time of Interview</u>
1. _____	_____
2. _____	_____
3. _____	_____

DOCUMENTS:

<u>Title of Document</u>	<u>Date of Document</u>	
1. <u>MINUTES OF PRODUCT EVALUATION CTTE</u>	<u>1990-91</u>	} REGARDING CRITIKON DEVICE
2. " " <u>HEALTH & SAFETY</u> "	<u>1990-91</u>	
3. " " <u>INFECTION CONTROL</u> "	<u>1990-91</u>	
4. <u>NEEDLESTICK STATISTICS</u>	<u>1990-91</u>	

Request received by _____

Date: _____

UNITED PUBLIC EMPLOYEES

LOCAL 790

Affiliated with the Service Employees International Union, the largest AFL-CIO Union in California

PAUL VARACALLI
Executive Director
MARGARET BUTZ SHELLED
Deputy Executive Director

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October 1, 1991

Richard Cordova, Executive Director
San Francisco General Hospital
1001 Potrero
San Francisco, CA 94110

RE: GRIEVANCE FILED ON BEHALF OF ALL RN'S STEP IV

Dear Mr. Cordova:

Pursuant to the Grievance Procedure of the Memorandum of Understanding between SEIU Local 790 and the City and County of San Francisco, we are filing a grievance at Step IV, Appointing Officer on behalf of all Registered Nurses. We are filing it at your level, because we believe that your level is the first that can remedy the grievance. If there is a lower level that has the authority please refer this grievance to them and inform me of it.

The Hospital has introduced the Protective I.V. Catheter made by Critikon into the Emergency Department and for Emergency Service. It was introduced because it is a safer medical device. Individual requests to use this device in other departments has been turned down.

In July of 1991, I requested hospital-wide usage of this device. To date this request has not been met. In March of 1991 a very serious needlestick injury occurred in the pre-op room. This needlestick could have been prevented if the Critikon device had been in use.

The Hospital is in violation of Section 32A Commitment to Safe and Healthy Work Environments and Section 31 Management Rights & Responsibilities of the Registered Nurse Memorandum of Understanding. It is not providing a safe and healthy work place. It also is not treating employees in an equitable manner. The Hospital has introduced the Critikon device in certain areas of the Hospital because it believes it to be a safer medical device. To prevent use in all areas of the hospital violates the above-mentioned sections of the Memorandum of Understanding.

The remedy we request is the immediate distribution of the Critikon device throughout San Francisco General Hospital and to conduct all necessary in-service training.

Richard Cordova
October 1, 1991
Page Two

We also request the following information and documents:

1. Minutes of Product Evaluation, Health and Safety and Infection Control Committee meetings where the Critikon device was discussed.
2. Comparative statistics on needlesticks with and without the Critikon device.
3. Statistics and information on which the decision to utilize the Critikon in the Emergency Department and Emergency Services was based.

Very truly yours,



Susan Rosenthal
Field Representative

SR: ps

cc: Janet Christensen, RN
Lorraine Thiebaud, RN
Peter Lurie, MD
Jolie Pearl., RN
Bill Charney
Diane Miller
Rod Auyang

opeiu29aflcio

Peter Lurie, MD, MPH
 Co-Chair, San Francisco Interns and Residents Association
 Testimony before Grievance Hearing
 on Critikon *Protectiv* Intravenous Catheter
 November 15, 1991

Ten years into the HIV epidemic, the frequently expressed sentiment that, in general, preventive measures are preferable to curative ones is still not being heeded at San Francisco General Hospital. The hospital has been justifiably lauded for its achievements in AIDS clinical care, finishing number one in a recent nationwide survey, and has been a leader in the investigation of post-exposure prophylaxis for occupationally-exposed health care workers.[1] However, despite one of the highest patient HIV seroprevalence rates in the country and two documented instances of occupationally-acquired infection, when it comes to the *prevention* of occupational exposures, SFGH's record is no better than average.

This statement has four parts. In the first the extent of the needlestick problem is briefly outlined. The second section lists administration rationale for failing to make the *Protectiv* available throughout the hospital. The third section addresses each of these rationales in turn. Finally, the *Protectiv* is placed in the larger context of overall hospital preventive strategies.

It should be emphasized that the preparation of this statement was greatly hampered by the lack of availability of key data. Despite multiple requests over a four month period, the administration has failed to provide current data on the rates of needlestick injuries and has only very recently made available data which purportedly justify the restriction of the *Protectiv* to the emergency room and ambulances.

A. EXTENT OF THE NEEDLESTICK PROBLEM

Reports of occupationally-acquired HIV infection are too numerous to be reviewed here. However, as noted above, at least two such cases have already been confirmed at SFGH. Because of

HIV's long latency and the difficulty in definitively establishing occupational causation, the numbers of proven occupationally-infected health care workers are likely an underestimate.

Many studies have reviewed the rates of needlestick injuries. We mention only the results of a recent study at UCSF. Nineteen percent of medical housestaff recalled percutaneous exposure to the blood of a known HIV-positive patient; 36% recalled similar exposure to a patient at high risk for being HIV-positive.[2] The authors concluded:

Thirty-one percent of the exposures in our study may be attributable to problems with equipment design. These included those from winged steel needles, intravenous stylets, and heparin locks. Therefore, our data support Jagger's conclusion that the best way to decrease the exposure rate to health care workers is to redesign blood drawing and intravenous infusion equipment so that health care workers' hands always remain behind the needle.

At SFGH itself, hospital data for Fiscal Year 1989 indicate that 7% of all needlesticks (20 of a total of 292 needlesticks) were associated with intravenous catheters. This number is certainly an underestimate. Two studies calculated rates of reporting to occupational health services of 4.3% and 60%.[3-5] At UCSF, among housestaff highly sensitized to the need for such reporting, only 30% of needlesticks were reported.[2] Using the UCSF underreporting estimates, the actual total needlestick figure for Fiscal Year 1989 may be as high as 973 of which 68 were due to intravenous catheters. Assuming a HIV seroprevalence rate of 15%, approximately ten of the sticks from intravenous catheters were from HIV-positive patients.

To understand the gravity of the problem, it is helpful to place the occupational risks for HIV acquisition in the context of job-related mortality for occupations generally acknowledged as hazardous. The annual risk of acquiring HIV for medical interns at UCSF has been estimated to be four and ten times as high as the annual risk of occupational mortality for California police officers and firefighters respectively.[2]

B. ADMINISTRATION ARGUMENTS

The following is an attempt to list all the arguments offered to date by the administration to justify restriction of the *Protectiv*. Sources of these arguments are meetings with the administration, press reports, and minutes of the Health and Safety and Product Evaluation Committees.

1. There is not universal agreement over the effectiveness of the *Protectiv*.
2. Intravenous catheters represent only a small percentage of neediesticks.
3. The emergency room is a "high-risk" area.
4. Greater disposal problems in the emergency room and ambulances justify restricting the device to only those parts of the facility.
5. The need for extensive training precludes greater availability of the device.
6. The *Protectiv* is too costly.

C. UNION RESPONSES

Argument 1: There is not universal agreement over the effectiveness of the *Protectiv*.

This argument raises two straw people. First, demonstrated effectiveness has not in general been a requirement for the introduction of new devices. We are puzzled as to why that standard has suddenly been raised here. Second, we cannot understand the sudden requirement for "universal" agreement. Certainly there is no universal agreement over the safety of the current intravenous devices. The unions' position has never been that existing intravenous devices be removed from the hospital; we have merely asked that the administration "immediately distribute the Critikon device throughout SFGH." This would permit employees a personal choice they are currently denied.

Fortunately, however, several lines of evidence now suggest that the *Protectiv* is indeed effective. ECRI, a Consumer Reports of

the medical device industry,* has recently conducted a review of needlestick-prevention devices (Attachment 1). The review concluded that the *Protectiv* "appear(s) to effectively reduce the risk of needlesticks" and "can be used to replace many common catheters." [6] It was the only device reviewed that received such unconditioned approval from the reviewers.

We assume from the decision to make the *Protectiv* available in the emergency room that the relevant SFGH committees came to the same conclusion. Nationwide, 283 hospitals currently using this device appear to concur; [7] 59 such hospitals on Critikon's "reference list" are appended. (Attachment 2)

Furthermore, we have obtained the results of the only field trial of the *Protectiv* ever conducted. (Attachment 3) Sentara Leigh hospital in Norfolk, VA used the *Protectiv* for a period of 14 months between April 1990 and May 1991. Their intravenous catheter-associated needlestick rates are as follows:

Period	<i>Protectiv</i> in use?	# Needlesticks	# Needlesticks/ # devices used
2/89-3/90	No	3	10.3/100,000
4/90-5/91	Yes	0	0/100,000
6/91-9/91	No	2	24/100,000

It would appear from these data that the *Protectiv* is indeed effective in preventing needlesticks. These results are statistically significant by Chi-Square ($p=0.047$).

Argument 2: Intravenous catheters represent only a small percentage of needlesticks.

SFGH data for Fiscal Year 1989 show that 7% of all needlesticks are associated with intravenous catheters. This figure is consistent with other studies in the literature. [2,5,8] However, this statistic neglects the fact that intravenous catheters are almost invariably contaminated and that they have large bore

* ECRI describes itself as "a nonprofit organization and the world's largest independent evaluator of biomedical equipment. Neither ECRI nor any of its employees accept financial support from manufacturers or distributors of medical equipment or technologies."

stylets. It is not altogether surprising, therefore, that two of the three documented seroconversions in the Centers for Disease Control cohort of occupationally-exposed health care workers[9] were infected by intravenous catheters.(Attachment 3)

The fact that a given device causes only a minority of needlesticks hardly negates the need for addressing them, particularly when they are preventable. Hospitalwide, Intravenous catheters were the fourth most common cause of needlesticks.(Attachment 4) in the only published study with device-specific rates of needlestick, Intravenous catheters ranked third among causes of needlesticks.[8] Furthermore, these same SFGH data show that even the device most commonly associated with needlestick injuries accounted for only 44% of such injuries. Thus needlestick injuries will have to be addressed on a device-by-device basis as better-designed instruments such as the *Protectiv* become available.

Argument 3: The emergency room is a "high-risk" area.

In order to assert that the emergency room is somehow "high-risk," one has to know how often procedures which place the operator at risk for percutaneous exposure are performed. This permits the calculation of a *rate* of needlestick per unit of use. The data provided by the hospital do not permit the calculation of such a rate and thus assertions based on these data as to which parts of the hospital are "high-risk" are speculative.

Indeed, the absence of a denominator (number of times a device is used) permits the kind of misleading statistical techniques upon which the administration has relied in making its case. Thus the fact that a high proportion of needlesticks in the emergency room and ambulances is related to intravenous catheters is hardly surprising when staff in those areas predominantly use intravenous catheters, even for the drawing of blood.

Published data show that only a small minority of needlesticks occur in the emergency room. Three studies reported a consistently low proportion of all sticks occurring in its emergency room: four percent,[8] five percent,[9] and 4.6%.[10] Although, for unexplained reasons, SFGH data suggest that 24.6% of needlesticks occur in its emergency room,(Attachment 5) any intervention that leaves unaddressed areas where three-quarters of needlesticks are occurring will have limited impact. Incidentally, it is hard to imagine any definition by which the ambulances, which account for

1.7% of all needlesticks would qualify as a "high-risk" area. (Attachment 5)

Argument 4: Greater disposal problems in the emergency room and ambulances justify restricting the device to only those parts of the facility.

It is self-evident that improved disposal systems can act to prevent only those needlesticks associated with disposal; sticks occurring during use, for example, will be unaffected by improved disposal facilities. SFGH data reveal that the largest proportion of needlesticks occur during use (44%) while only a small fraction (14%) take place "before/during disposal." This proportion is actually somewhat lower than studies in the medical literature which report proportions of disposal-related needlesticks of 18-24%. [11-15] It is not surprising, therefore, that four published studies fail to document significant decreases in total needlesticks when either disposal systems were improved or universal precautions were introduced. [11,12,14,16]

In fact, there seems to be little difference between needle disposal systems on the wards and in the emergency room. Except in the three trauma rooms where large sharps containers stand beside the walls, disposal facilities in the emergency room seem identical to those on the wards. Thus even if one believed (erroneously) that sharps containers would eliminate a substantial proportion of the problem, the current disposal systems at SFGH would seem to offer little justification for restricting any potentially safer devices to the emergency room.

Argument 5: The need for extensive training precludes greater availability of the device.

The minutes from SFGH's Product Evaluation and Health and Safety Committees acknowledge the problems of restricting the *Protectiv* catheter.

Product Evaluation Committee, 11/5/90: "Committee agreed that the catheter needs to be used throughout the house as a safety device for all staff. A major drawback is technique. Staff **MUST BE TRAINED AT ALL LEVELS ACROSS THE BOARD.**" (emphasis in the original)

Product Evaluation Committee, 12/3/90: "This committee agreed that isolated areas of usage would create confusion, and increase inservice problems. . . Resolution: **WILL NOT PURCHASE AT THIS TIME.**" (emphasis in original)

Health and Safety Committee, 12/5/90: "Needles will not be phased in due to Inservice problems and inability to provide proper training prior to using."

Product Evaluation Committee, 2/4/91: "Ctee. decided to purchase the Criticon (sp.) protective device for the EMS & ER ONLY. This will require intensive in-service for physicians, and staff in the ER. . . Concerns are that the cath. will get into other areas of the hospital." (emphasis in original)

In fact, current SFGH in-service training leaves much to be desired. As the Health and Safety Committee minutes of 9/4/91 note, "Medical staff not being inserviced on safety devices, particularly ER." As a family physician who has worked throughout SFGH, I have never had in-servicing on how to use any phlebotomy or intravenous equipment in the emergency room or elsewhere; the sudden appearance of this issue is spurious, at best.

Indeed, the use of Inservicing problems as a justification for device restriction seems to us an attempt to circumvent the provisions of California SB198 which requires training for new pieces of hospital equipment. If the problem is the need for training, let there be training, not device restriction as is the current practice.

Argument 6: The *Protectiv* is too costly.

At a labor-management meeting on 9/11/91, Deanna Mooney, CPD supervisor, stated that it would cost an additional \$172,000 to phase in the *Protectiv* throughout the hospital. This figure seems to us a substantial overestimate. Thus far SFGH has only purchased 14, 16, 18, and 20 gauge *Protectiv* catheters. Since 90,179 regular (Gelco) intravenous catheters are used annually at SFGH[17] and the price differential is \$0.96 (\$1.50-\$0.54[18]), the wider availability of the *Protectiv* would only cost \$86,572 per year. Even if *Protectivs* replaced all 22 and 24 gauge intravenous catheters (a further 20,784 catheters per year), the total annual cost would only be \$106,524. These estimates represent 0.027% and 0.033% of the current hospital budget.

These cost estimates do not account for savings produced by the potential prevention of needlesticks. If the cost of managing each needlestick is \$405,[19] the 20 reported intravenous catheter-related needlesticks per year are likely costing SFGH about \$8100 annually. These estimates exclude the provision of zidovudine (AZT), which although free to SFGH at the present time is unlikely to remain so once the current trials are completed.

Failure to adequately protect employees places the hospital at significant liability risk. In addition to footing the bill for Worker's Compensation benefits, the hospital is at risk for being the target of a tort suit. In a New York City teaching hospital, Veronica Prego received \$1.3 million after acquiring HIV through a needlestick. A recent suit against a medical device manufacturer for designing a defective blood collection tube suggests that hospitals are potential "deep pockets" in such suits.[20]

Finally, in addition to the obvious benefits of preventing HIV and hepatitis B infection, the psychological costs to workers must be considered. Exposed workers must endure up to six months of uncertainty during which such fundamental questions as whether to continue working, whether to have sexual relations with one's partner or whether to abort a fetus are raised. The toll of such experiences is incalculable.

D. CONCLUSIONS

All six of the administration's arguments have thus been examined in turn and found wanting. The *Protectiv* Intravenous catheter should immediately be made available throughout the hospital along with suitable in-service training. This should be part of a wider strategy that would include greater accessibility of free hepatitis B vaccine, the institution of intravenous teams and the expansion of phlebotomy teams, sensible limitations on housestaff hours, and the expansion of benefits packages to include disability insurance.

The time has come to implement the Occupational Safety and Health Administration's Compliance Guideline which states in part:

Engineering controls should be used in preference to other control methods to eliminate or minimize worker exposure to blood or other potentially infectious materials. . .

Examples of engineering controls include but are not limited to: puncture-resistant sharps containers, splash guards, mechanical pipetting, and self-sheathing needles.[21]

The debate over the wider availability of the *Protectiv* provides SFGH with a unique opportunity to become a leader not only in AIDS treatment and post-exposure prophylaxis, but also in the vital realm of exposure prevention.

Endnotes

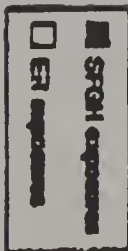
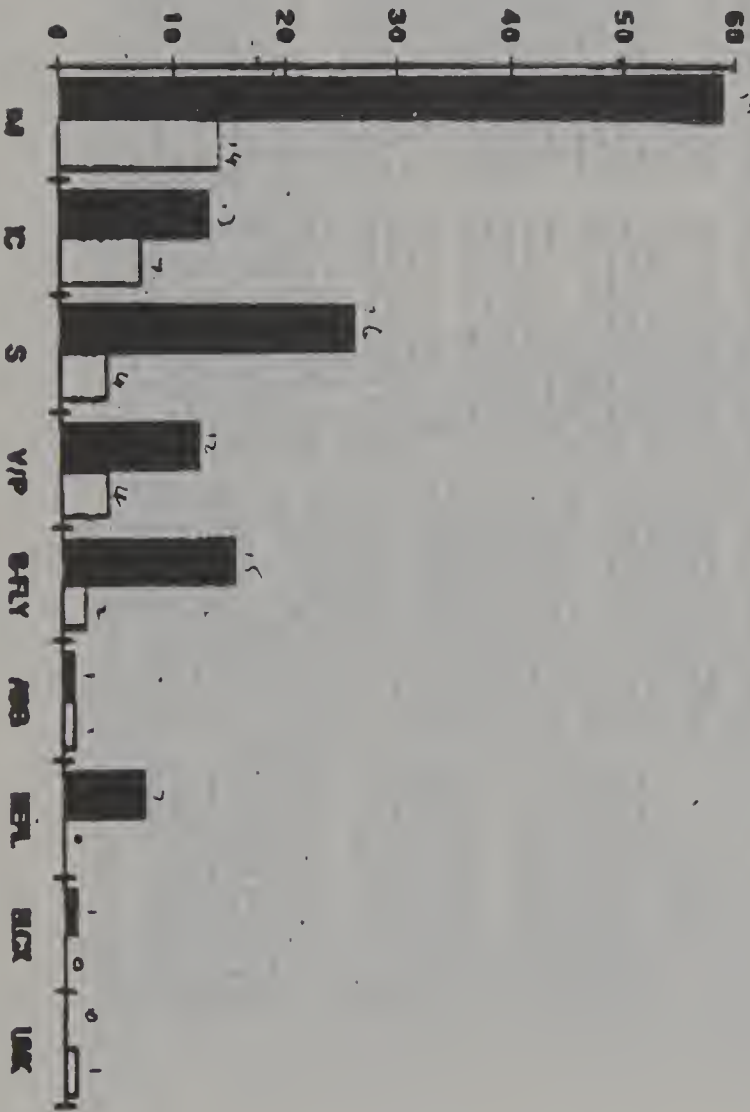
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ATTACHMENT 4

Numbers

Emergency Dept and SFGH Needmatch Comparison



Boston Globe 9/28/91

Health worker sues over AIDS infection

St. Louis firm's equipment for drawing blood is blamed in suit

By Efrain Hernandez Jr.
GLOBE STAFF

A health care worker from North Attleborough who says she was diagnosed with the AIDS virus after being stuck by a needle while taking blood from a patient is suing a St. Louis medical supplies company for allegedly making dangerous equipment.

Merline Foster, 47, who works at Southwood Hospital in Norfolk, filed the suit Thursday in US District Court in Boston. Foster's lawyer, Jeffrey A. Newman of Boston, said the Sherwood Medical Co. of St. Louis received the complaint yesterday.

The complaint states that Foster, a phlebotomist, was drawing blood from an AIDS patient at Southwood Hospital on July 24, 1990, when a blood collection tube manufactured by Sherwood Medical Co. cracked. Foster came in contact with the patient's blood and months later was diagnosed as being HIV positive, it states.

Foster, who said yesterday that one of her fingers was pricked by the needle, said that she feels her life has been turned upside down. She now works with medical records at the hospital, rather than with patients.

"My life will never be the same again from this point. I feel like I'm never going to be happy again," said Foster, a single mother whose 21-year-old daughter lives in Boston. "You constantly wonder, are you going to get sick? How many years have you got? It's like getting a gun to your head and playing Russian roulette."

The suit alleges that equipment made by Sherwood Medical and used by Foster, specifically the blood collection tube and the needle holder, was defective and dangerous and that the company knew or should have known that.

"The defendant, Sherwood, owed a duty of care to ensure the safety of its product but, in disregard of their duty, Sherwood allowed the tube to enter the stream of commerce in an unsafe and inherently defective and

dangerous condition," the suit states. Because of Sherwood's negligence, the suit states, Foster "was caused to contract the HIV virus."

Foster is suffering severe psychological and physical damages and is incurring "substantial medical bills," the suit states.

Company officials did not return a telephone call yesterday afternoon. A company lawyer told the Associated Press yesterday that he had not seen the complaint and could not comment.

The suit, Foster and Newman said, does not seek specific damages because that should be determined by a jury if the company is found guilty. "I'm not worried about money. Money is not the situation," Foster said, emphasizing what she said was the need for more people to take seriously the fight against AIDS. "Everyone has to take total responsibility from A to Z. If that's not done, we're not going to control this virus."

She and Newman said that among the goals of the suit is to encourage the use of safer products for

the good of patients as well as health care workers.

The federal Centers for Disease Control reported this year that there are about 40 health care workers in the nation infected with HIV through accidents related to work.

Foster, who said she has never been a drug abuser or had multiple sexual partners, two of the ways in which the virus is transmitted, said she tested positive for the HIV virus in May.

"I talked to my priest about it first," she said. "I have a lot of support. I have support from my family and I have really wonderful friends. And the employees and the doctors are great."

But her stress and uneasiness is always present, she said.

"You lose so much. You lose your self-esteem. If it wasn't for my faith, I don't know if I could go on. I really mean that," Foster said. "I don't even know how to act with people. I don't know what people think. Mentally, you're on a roller coaster."

ATTACHMENT 3
UNIVERSITY OF VIRGINIA



HEALTH
SCIENCES
CENTER

DEPARTMENT OF
NEUROLOGICAL SURGERY

November 13, 1991

Linda A. Chiarello
AIDS Program Manager
Office of Public Health
State Department of Health
Empire State Plaza
Albany, NY 12237

Dear Linda:

I would like to follow-up our conversation regarding the New York State pilot study of the Critikon ProtectIV™ intravenous catheter and the favorable experience you have documented to date. First, your focus on the hazards of I.V. catheter stylets is well founded, because these injuries involve large bore, blood-filled needles. Not surprisingly, two out of three HIV seroconversions in the CDC needlestick surveillance study were caused by I.V. catheter stylets of conventional non-protective design.

What may be of interest to you is information on the experience of Sentara Leigh Hospital in Norfolk, Virginia which has documented more than one year of hospital-wide use of the ProtectIV™ catheter. A nurse on the I.V. team, Jamie Winner, and the Director of Employee Health, Karen Ward-Lilly, documented I.V. catheter use, and I.V. catheter stylet injuries before, during, and after the period during which the safety catheter was in use.

I learned of their situation in June of 1991 when the hospital administration, without consultation of nursing or medical staff, and despite emphatic objections, decided to revert back to conventional non-protective catheters and to pull the remaining stock of the ProtectIV™ catheters from all areas of the hospital. Nurses from the IV team collected a few hundred remaining ProtectIV™ devices, and have been doling them out sparingly for special situations since June. They continue to press for a reversal of the hospital's decision, and recently provided me with the following information, which is, I believe, the most extensive documentation that currently exists on the use of the ProtectIV™ catheter.

Sentara Leigh is a 250 bed hospital, using about 25,000 I.V. catheters per year. Before April of 1990 the hospital used standard Jelco™ I.V. catheters. From April 1990 through the end of May 1991 (14 months) the ProtectIV™ catheter was used hospital-wide. In the middle of June 1991 the ProtectIV™ catheter was removed from all areas of the hospital and replaced by the Jelco™ I.V. catheter and has been in use since that time. During the 14 months preceding the introduction of ProtectIV™, three I.V. catheter stylet needlesticks were reported to the Employee Health Department, a rate of 10.3 per 100,000 catheters in use. Interestingly, that is in a similar range to the rate of

18.4 injuries per 100,000 catheters that we documented at the University of Virginia in 1986^a (a non-protective design). During the 14 months that ProtectIV™ was in use at Sentara Leigh there were no I.V. catheter stylet injuries documented in Employee Health records. During the four months after the Jelco™ catheter was reintroduced from June through September 1991, two I.V. catheter stylet injuries were recorded with Jelco™ catheters; a needlestick rate of 24 per 100,000 catheters used. The difference in injury rates between Jelcos™ and ProtectIVs™ is statistically significant. A graph of this data is presented below.

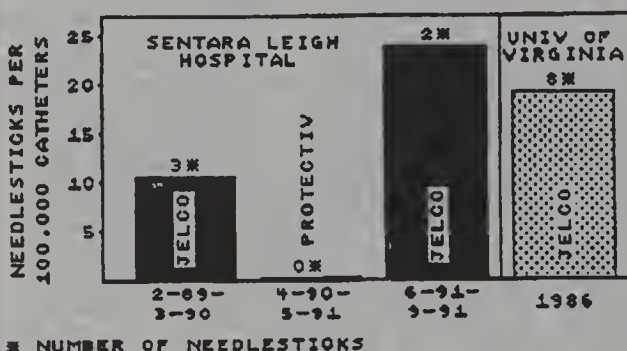
I hope you find this information useful. Please keep me informed of your progress in evaluating the ProtectIV™ catheter and other needlestick protective devices in New York State. I am certain your efforts will be rewarded by an acceleration of the pace at which hospitals are willing to provide new, and safer technology to health care workers.

Sincerely,

Janine Jagger
Janine Jagger, M.P.H., Ph.D.

Associate Professor of Neurosurgery

IV Catheter Stylet Injury Rates with Conventional and Protective Catheters



Note: The number of devices tested meets statistical sample size requirements (based on 5 injuries per 37,000 Jelcos™ used versus no injuries per 29,000 ProtectIVs™ used.) $\chi^2 = .047$.

^a Jagger J, Hunt EM, Brand-Elnaggar J, Pearson RD. Rates of Needle-stick Injuries Caused by Various Devices in a University Hospital. *New England Journal of Medicine* 1988;319:284-86.



Boston University
School of
Public Health
in the School of Medicine

Health Services Department

80 East Concord Street
Boston, Massachusetts
02118-2394
617 638-5042

November 18, 1991

Richard Cordova
Chief Executive Officer
San Francisco General Hospital
1001 Potrero Avenue
San Francisco, California 94110

Dear Mr. Cordova,

San Francisco General Hospital is well known throughout the national community for its progressive practices and leadership around the care of the individual who is HIV positive and those that have progressed to AIDS. I have just returned from a national meeting of the American Public Health Association in Atlanta, and am troubled by an account of an incident that has arisen at your institution. It is unfortunate that nursing staff must seek a union arbitration hearing over workplace safety. This is a management responsibility. The AIDS unit seeks to have the same retractable IV catheter that is available in the Emergency Department, and now must fight to have it. This is representative of the gap between theory and reality.

As you know, every needlestick is a serious event, and every potential needlestick has a high consequence including cost for followup, and costs related to turnover, workman's compensation and recruitment. Eliminating the hazard through management enforcement of universal precautions and the use of personnel protective barriers must be a management priority. As leaders in healthcare we must look to protecting our workers at every opportunity especially if we know the risks. When the risks increase with low morale due to staffing patterns and a high case-mix, then we must as leaders provide a safe workplace for our front-line workers if they are to remain in place. We can't afford to wait. All patients must be viewed as potentially infectious for HIV or HBV.

Your leadership on this issue is paramount as many have looked to San Francisco General for guidance. If the capability exists to have a needleless system, and systems that protect the workforce in high risk procedures, especially in high risk populations, let's use them. I look to you for your leadership practice and role modeling. Closing this gap between theory and practice could alleviate injury, and thus sero-conversion. Even with a low sero-

conversion risk there are very high consequences. As a public health professional and educator, and a former hospital Director of Nursing, I understand the system constraints. I look to you for a proactive response. May you do all that is possible to protect your workforce. I look forward to hearing from you. Thank you.

Sincerely,

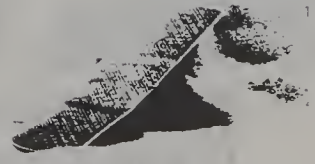
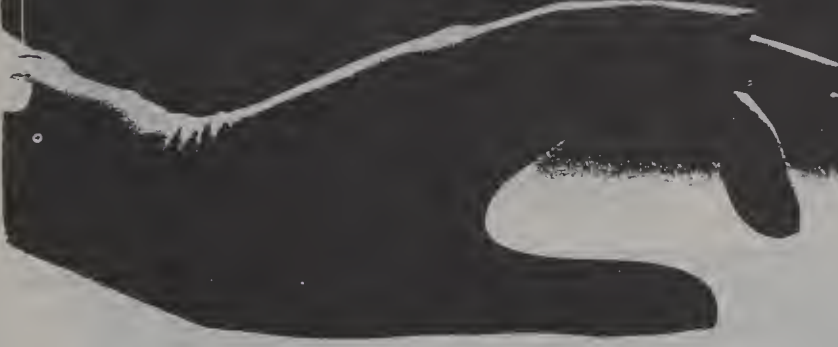


Gail Douglas R.N., M.P.H.
Assistant Professor of Public Health, Health Services
Associate Chair, Health Services Department
Boston University School of Public Health

cc: Brenda Lauer
Director of Nursing

PROTECTIV™ I.V. Catheter Safety System

Getting To The Point
Of Needlestick Injuries
And The Resulting Risk
Of AIDS And Hepatitis.



CRITIKON

a Johnson & Johnson company

Protection Against Built In. I

The PROTECTIV[®] I.V. Catheter Safety System Puts Needlestick Protection In Your Hands.

Needlesticks account for more than a third of all hospital-related injuries¹ and *eighty percent* of HIV/AIDS and HBV infections acquired on the job; facts that have underscored the need for a product to help prevent needlesticks.

The PROTECTIV[®] I.V. Catheter Safety System is the product the medical profession has been calling for — a catheter that can be used and disposed of with no risk of needlestick.

As you slide the catheter off the introducer needle, the protective guard slides into place over the needle. You are

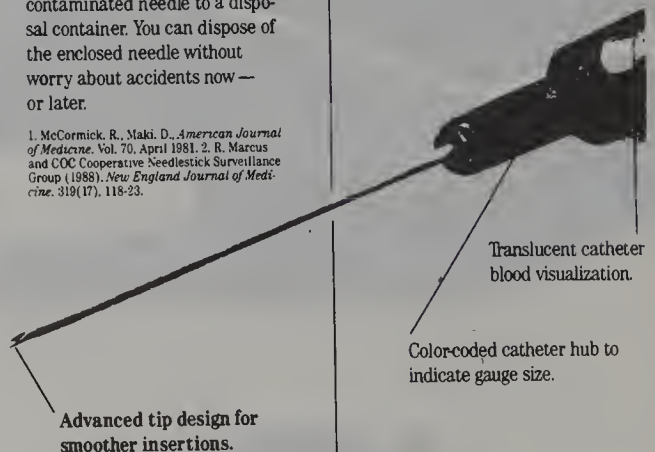
never exposed to a contaminated needle because the guard locks into place over the needle before the needle is removed from the catheter hub.

A reassuring "click" lets you know the needle has been safely and permanently locked within the guard. No need to recap. No need to transport a contaminated needle to a disposal container. You can dispose of the enclosed needle without worry about accidents now — or later.

1. McCormick, R., Maki, D., *American Journal of Medicine*, Vol. 70, April 1981. 2. R. Marcus and COC Cooperative Needlestick Surveillance Group (1988). *New England Journal of Medicine*, 319(17), 118-23.

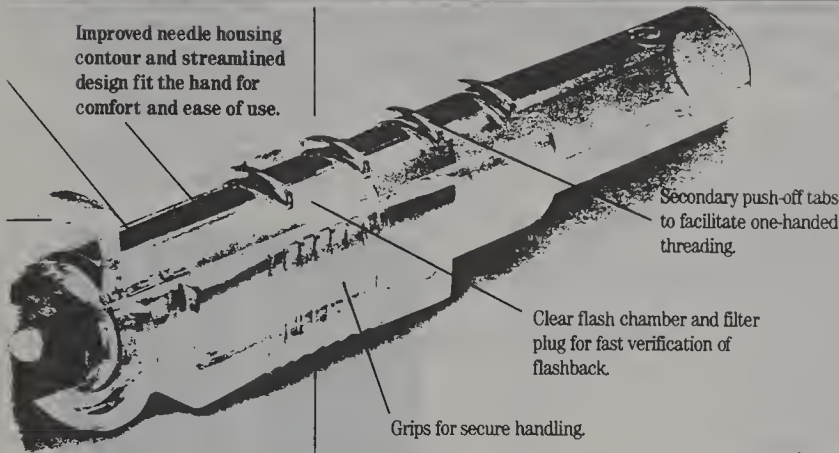
Built-in guard to encase needle point.

A push-off tab allows you to thread the catheter with one hand, while keeping your hand behind the needle, out of harm's way.



The Standard of Protection In Today's Environment.

Needlestick Injury. Locked In.



PROTECTIV™ I.V. CATHETER SAFETY SYSTEM

Three-Step Procedure



1. **INSERT.** Using standard procedure, insert the I.V. catheter. Then, position forefinger behind push-off tab to begin threading the catheter.



2. **SLIDE AND LOCK.** Slide the catheter off the introducer needle while gliding the protective guard over the needle. Listen for the "click" that tells you the needle is safely locked in place.



3. **DISPOSE.** Remove the encased, locked needle from the catheter hub and dispose of it.

We've Smoothed The Way To Easier Insertions.

Advanced Tip Design.

The tip on the PROTECTIV™ I.V. Catheter Safety System has been improved in three important ways to give you a more consistent and easier insertion...and to make it more comfortable on your patients.

First, the catheter shoulder has a more finely beveled tip and sleeker profile, to make it less likely to "catch" going through skin.

Secondly, the trim accuracy has been improved. By decreasing and consistently controlling the distance from the catheter tip to the heel of the needle, we've made a catheter that you can insert with one smooth, confident motion, with reduced risk of entry problems.

And thirdly, a new molding process makes the catheter tip uniformly strong, eliminating any "weak" points...and resisting the tendency to peel back.

-Finely beveled shoulder on the advanced tip smooths insertions while minimizing tissue trauma and complications.

-Improved trim accuracy (distance from the catheter tip to the heel of the needle) reduces the risk of vein entry problems.

-New molding process provides a uniformly strong catheter tip that is less likely to "peel back" during insertion.

-Catheter flexes without obstructing fluid flow.

-Super-sharp introducer needle facilitates skin penetration.

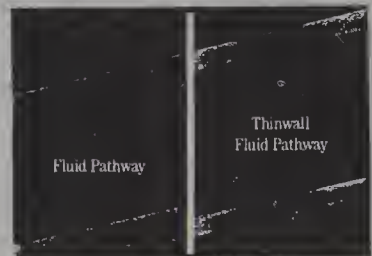
-Buffered inner heel of needle reduces chances of coring and patient discomfort.

-Thinwall construction creates larger lumen, permitting higher flow rates, gauge for gauge.

Thinwall Construction For Better Flow Rates.

Thinwall construction allows you to trade down to a smaller catheter while still maintaining adequate flow rates. This not only improves patient comfort, but also increases the number of available veins.

Smaller catheters also minimize contact with the vein wall, reducing the threat of indwelling complications.



The advanced tip design provides a uniformly strong catheter tip that is less likely to "catch" on tissue during insertion.



Other tip designs have shoulders that may catch, or weak points that are susceptible to peelback.



-Translucent color-coded plastic hub indicates catheter gauge at a glance.

Ordering Information

Catalog

Number	Description
3053	24g x ¾"
3050	22g x 1"
3057	20g x 1"
3056	20g x 1¼"
3055	18g x 1¼"
3042	16g x 1¼"
3048	14g x 1¼"

CRITIKON

a **Johnson & Johnson** company

The Worldwide Leader in I.V. Catheters

Critikon, Inc. P.O. Box 31800, Tampa, FL 33631-3800

For ordering or customer service 9 A.M. to 8 P.M. EST please call:
Johnson & Johnson Hospital Services at 1-800-255-2500.
For automated order entry information: 1-800-282-2888

Testimony of
Gwyen Spruill
Medical Laundry Transport Worker
Wayne, Michigan

Healthcare Worker Safety and Needlestick
Injuries

to the
House Committee on Small Business
Subcommittee on Regulation, Business Opportunities,
and Energy
February 7, 1992

Good morning. My name is Gwyen Spruill, and I am a steward for Local 79 of the Service Employees International Union. I am grateful for the opportunity to come here today in support of safer medical devices.

I work as a transporter for a laundry facility in Wayne, Michigan, just outside of Detroit. This laundry facility provides full laundry services to eight Detroit area hospitals. My job is to transport soiled lined from the hospitals and unload it at the laundry for sorting and cleaning.

You might think that because we work in a laundry, with no direct patient contact, that we are not at risk for contracting infectious diseases like hepatitis B or HIV. The truth is the laundry workers, housekeepers, food service workers, and other so called "downstream workers" are often exposed to used needles, scalpels and other surgical instruments that are contaminated with blood.

Let me tell you what it's like working in a hospital laundry. It's not unusual to pull up to a dozen needles, lancets, and scalpels out of the laundry every month. We've had whole used IV systems with dangling needles show up in the laundry. Once, an entire surgical tray with over 150 used and bloody instruments on it came through wrapped up in the linens. We were averaging at least half a dozen reported needlesticks per year. Both myself and the other steward have received needlestick injuries. To date, we both have tested negative for HIV and HBV.

This is what would happen when one of us got stuck with a sharp. The worker would be sent to the clinic and given a few shots. I guess they were for tetanus and hepatitis B, but most of the time they didn't even bother to tell you what they were treating you for. Then the worker would be handed a bag of condoms and told to use them for the next six months. There was no medical follow-up. I can't even put into words how stressful this kind of treatment has been for many of my co-workers. At that time, there was no follow-up training or support. There was no plan for ensuring it would not happen again.

Several years ago, myself and another union steward, Sue Hickman, began dealing with the problem of needles and other sharps coming through mixed in with the laundry. It's been a long, hard fight, and it's not over yet. I first approached management in 1989 for some kind of protection against all the needlesticks that co-workers were getting. When management failed to respond or come up with a plan, I began saving all the sharps that came through the laundry for documentation, and filed a complaint with Michigan OSHA. Within just two weeks, we collected over 200 needles, scalpels, scissors, and other sharps from the soiled laundry. The photos I've attached were taken by Michigan OSHA during their initial

inspection in February 1990. Michigan OSHA cited the hospital that was the source of most of the sharps we collected. After that first inspection, the number of sharps coming through dropped off for a few weeks. But now, two years later, the hospital is still appealing the citation and we're still getting stuck with needles. I brought here today what we've pulled out of the laundry just in the last few weeks.

I think it's great that OSHA released the bloodborne disease standard this past December and that universal precautions are now the law. Because of our union's grievance procedure and our own efforts to get the law enforced, we now have been trained on universal precautions and we get hepatitis B vaccine free of charge. We even have latex gloves. But, the bottom line is that needles and sharps just keep coming.

It's a fact that most needlestick injuries occur at or after the point of disposal and for workers like me who work at the end of the healthcare line, engineering controls like self-sheathing needles give us the best, and sometimes the only protection.

The latex gloves we have offer no protection against needles. And while Michigan OSHA ordered our employer to provide us with puncture resistant "kelvar" gloves over a year ago, we've yet to see them.

I would like to see the CDC and FDA recommend that needles and other sharps have lock-out devices on them and that healthcare workers be trained on how to use them.

I've served in Vietnam. Going to work where I can be stuck with bloody needles is more stressful than that was. I think it's wrong that I should have to put my life on the line every day just to earn a living.

Thank you.

Attachments for Testimony of Gwyen Spruill

February 7, 1992

Report of Alleged Occupational Health Hazards

Michigan Department of Public Health
Division of Occupational Health

MOD Date		1. Complaint Number	
		073133449	
2. Employer Name United Care (formerly PCHA) Central Laundry			
3. Site Location (Street, City, State, ZIP) 33000 Annapolis Wayne MI 48184			
4. Mailing Address (if different) (Street, City, State, ZIP) 33000 Annapolis Wayne MI 48184			
5. Management Official Art Witlow		6. Telephone Number (-) -	
7. Type of Business Healthcare, Laundry oper.			
8. Hazard Description. Describe briefly the hazard(s) which you believe exist. Include the approximate number of employees exposed to or threatened by each hazard: Laundry frequently contains infectious waste which includes placental tissue, post operative matter, needles, scalpels, etc. The facility has failed to develop an infection control program which includes employee training on universal precautions. Latex gloves are available buy only one size and are too tight for workers with larger hands. Sharps are not being placed in puncture resistant containers for disposal but are instead mixed in with the linens. Putrescible waste has not been removed in a timely manner but allowed to build up for weeks. Thus creating a menace to workers health. Masks are not available when working with decomposing post operative waste.			
9. Hazard Location. Specify the particular building or worksite and the workshifts where the alleged violation exists: U.C. Central Laundry, 33000 Annapolis, Wayne, MI 48184. first shift. Contact stewards Susan Hickman and Gwyn Spruill to participate in MIOSHA walk through inspection.			

File - White
Interviewee - Blue

Michigan Department of Labor
Bureau of Safety and Regulation
State Secondary Complex
7180 Harris Drive, Box 30015
Lansing, Michigan 48908

INTERVIEW STATEMENT

☒ G.I.☐ C.S.

Page 1 of 1
Job No. 110 941 CSI
S.O. TRDD
County WAYNE
Contact Date 04/29/91
Time _____

UNITED CARE - CENTRAL LAUNDRY EMPLOYEE COMPLAINT
(Name of Interviewee) (Purpose of Interview)
I, SUSAN HICKMAN
44064 PARSONS Belleville MICH 48111 Telephone No. 313-695-5711
(Address) (City) (State) (Zip)

☐ (was)

☒ (am) employed by UNITED CARE - CENTRAL OFFICE
(Name of Employer)
whose address is Ann Arbor Wayne MICH
(Complete address of employer)
From OCT 1 1987 to PRESENT (If still employed, state "present")
My occupation is a washer ATT. in CENTRAL LAUNDRY Department

We at the laundry have try and try to get something done with NCS SHARP PROMBLEM. Last year we found a lot of STUFF (needles, razors, scissors, and other things) that was being sent through the laundry every day. I got a log and it showed that most of the things were from a certain management and that they told us the security would be taking care of it. And a lot of the problems were all most stopped. But in the past few months it has started to get bad again. So we keep reporting it and reporting it. Till it got to the point where we felt something was going down. So we place a call to this office. Then we started to place the stuff in a box again. Here is a list of what we got in 2 weeks.

2 4" needles	1 Bland Haldor
2 1/2" needles	3 Wounde Haldor
1 round needles	6 RAZER
1 long Hook needles	7 S. Scissors
2 Shaving w/ needles	7 Clamps
3 Shaving	2 T.V.'s cards
	1 Twister

"I have read the above and it is true."

Susan Hickman
(Signature of Interviewee)




UNITED CARE, INC.
Inter - Office Memorandum
Central Office

TO: See Distribution

DATE: March 1, 1990

SUBJECT: Needles & Sharps in Linen
Returned from the Hospitals

FROM: Art Whitlow 
Central Laundry Manager

All employees of the Central Laundry are to immediately notify a supervisor when a needle or sharp object (i.e., scalpel blade, surgical instruments, etc.) is found in the linen that is returned from the hospitals.

Please indicate to the supervisor where the item was found so the responsible hospital can be held accountable. The supervisor will take the item to the office immediately to be placed in a sharps container and recorded on a designated log sheet. If the hospital is positively identified the supervisor will notify the designated representative at the hospital. All needles and sharps should be properly disposed of at the hospitals.

cc: Central Laundry Employees
Central Laundry Supervisors
Mr. Dave Hoff
Personnel
Infection Control Manual
Posting Board

UNITED CARE

33000 Annapolis Avenue
Wayne, MI 48184-2492
313-467-4600
Fred E. Blair, Chief Executive Officer

August 14, 1989

Annapolis Hospital
33155 Annapolis Avenue
Wayne, MI 48184
313-467-4000

Bayer Hospital
135 South Prospect Street
Ypsilanti, MI 48198
313-484-2200

Heritage Hospital
24775 Haig Avenue
Taylor, MI 48180
313-295-5000

Outer Drive Hospital
26400 Outer Drive
Lincoln Park, MI 48146
313-386-2000

Seaway Hospital
2450 Fort Street
Trenton, MI 48183
313-671-3800

Mr. Jerry Derowski
Director of Material Services
Oakwood Hospital
18101 Oakwood Boulevard
Dearborn, MI 48123-2500

Dear Jerry:

Our laundry facility has been having a problem with contaminated needles being returned in the soiled linen from Oakwood Hospital. When this ongoing problem was brought to my attention, I instructed our soiled sorting personnel to identify the account or accounts that were returning needles in their soiled linen. Oakwood Hospital was the only account reported by the staff. There have been four incidents of puncture wounds this year, the most recent occurring on August 6. I have attached a copy of the incident report for your review. I will also present the collection of needles we have recently found in your soiled linen when we meet tomorrow. With the implementation of universal precautions all needles, syringes, and other sharps must be removed at the hospital and properly disposed. In today's healthcare environment puncture wounds present a serious threat to employees and every effort must be made to prevent such incidents. I would appreciate every effort you can make to a successful resolution to this problem.

Sincerely,

Art Whitlow

Art Whitlow
Central Laundry Manager
United Care Inc.

cc: Mr. David Hoff
Mr. Keith Lees
Mr. Gwyn Spruill

DEFINITION: An Employee Incident is any event which has or could have resulted in injury or illness to an employee. This report is not to be used for patient or visitor incidents.

INSTRUCTION: Employee's supervisor completes sections 1, 2, 3, 4 and 6. Treating physician or Employee Health Nurse completes section 5. Department Head reviews for completion before submission to Administration.

2. INCIDENT DATA

INCIDENT DATA
a Exact Incident Location Washroom Area
b Date 8 / 6 / 89 c. Time 10 : 40 (24 hr clock)
d Witnesses _____
(name & dept.) _____

a. Nature of injury/illness and part of body injured Left Hip Area
b. Patient involvement ☒ No ☐ Yes Patient Name _____ Case # _____ Room _____
c. Causative agent most directly related to incident (object, substance, equipment, material, conditions, intangible, etc.)
Dirty Needle

d. Physical/environmental condition(s) contributing to the incident None

e. Unsafe act(s) by injured and/or others contributing to the incident: None

f. Other contributing factors None

Employee was dumping bage of dirty linen on the conveyor and was etuck in the hip area with a contaminated needle.

Arch. J. Guj 8, 6, 8
 Signature of Person Preparing Report Date

LOCATION: ☐ Emp. Health ☐ ER ☐ Other _____

PHYSICIAN'S STATEMENT REGARDING CONDITION OF EMPLOYEE INVOLVED AFTER THE INCIDENT

☐ Lab ☐ X-Ray Requested? Results: _____

Is this incident the only probable cause of the patient's condition? ☐ Yes ☐ No Patient (was) (will be) able to resume work ____ / ____ / ____ Restrictions & Duration: _____

Signature of Treating Physician _____

Referral ☐ Yes ☐ No to Dr. _____Re-evaluation ☐ Yes ☐ No by Dr. _____Appointment: ____ / ____ / ____
DateTime

Signature of Employee Health Nurse

6. **SUBSEQUENT ACTION** Taken by Supervisor, Department Head to prevent the occurrence of a similar event. (Use additional sheet if necessary).

Name Cecily Gray Date 8/6/88
 Supervisor _____
 Department Administration
 Administration _____

7. To be completed by Personnel Department
a Mos since last incident _____ b Mos of Service _____
C Mos. on present job _____ d. Incident # _____

STATE OF MICHIGAN



JAMES J. BLANCHARD, Governor

DEPARTMENT OF PUBLIC HEALTH3423 N. LOGAN
P.O. BOX 30195, LANSING, MICHIGAN 48909

Raj M Wiener, Director

May 25, 1990

SIC #7211
C#108047861
#073133449Reply to:
7325 Middlebelt
Westland, MI 48185United Care Central Laundry
33000 Annapolis
Wayne, Michigan 48184

Attention: Art Witiow, Manager

On March 21, 1990, a representative of this Division conducted an investigation at your laundry facility in response to a complaint concerning infectious wastes that were being generated by different hospitals that are clients to your laundry business operations. An opening conference was held with Mr. Art Witiow, Manager; Mr. Gwyn Spruiell, Union Representative; and Ms. Susan Hickman, Assistant Union Representative, during which we explained the purpose and procedures of our investigation along with various aspects of the MIOSHA Act.

A walkaround of the area was conducted and pertinent occupational health programs were reviewed. A closing conference was held with the above named personnel during which preliminary investigation results were reviewed. Proposed violations of the Michigan Occupational Health Standards were explained as were methods and dates of abatement, penalty, and appeal process.

INSPECTION FINDINGS

During the opening conference we inquired about your company's compliance with the Michigan Hazard Communication Standard (Right-to-Know Law). The intent of the Michigan Hazard Communication Standard is to ensure that the potential hazards of all chemicals produced or imported by chemical manufacturers or distributors are evaluated and that information concerning the hazard is transmitted to the employees who may be exposed to these materials in their workplace. The objective of the Michigan Hazard Communication Standard is to reduce the incidence of chemically related industrial illnesses and injuries.

The Michigan Hazard Communication Standard encompasses four general areas: development of an effective written hazard communication program; compilation and maintenance of material safety data sheets from chemical manufacturers and

United Care Central Laundry
May 25, 1990
Page 2

distributors; labeling of chemical containers or container systems in the workplace identifying the appropriate chemical hazards; and providing information and training to the employees for the hazards of the chemicals to which they may be exposed.

During the investigation, we reviewed the company's hazard communication program and we determined two violations of the Michigan Hazard Communication Standard. Accordingly, a citation is issued which requires your company to:

- . Provide a written hazard communication program.
- . Provide employees with information and training concerning hazardous chemicals.

A copy of the Michigan Hazard Communication Standard is enclosed for your information.

Additional information revealed that employees who work as custodians in your facility have available respirators with cartridges (approved #TC-23C-210 and #TC-21C-175) when necessary for their work. Although you have provided respirators to protect your employees, you have not developed a program regarding respirator use. Some of the requirements of a minimal acceptable respiratory protection program are:

- . A written operating procedure covering the selection and use of respirators must be established. Only NIOSH approved respirators must be selected.
- . Employees must be instructed and trained in the use, care, and limitations of respirators.
- . Respirators should be assigned to individual workers and not shared unless adequately cleaned and disinfected before assignment.
- . Respirators must be cleaned and disinfected regularly.
- . Respirators must be stored in a clean and sanitary location such as plastic zip-lock bags.
- . A physician must determine if an employee is able to work and wear a respirator without physical limitations.

Since a respiratory protection program was not in place during our investigation, the enclosed citation is issued for violation of Rule 3502 (i)(b). A copy of this rule has already been sent for your information.

United Care Central Laundry
May 25, 1990
Page 3

During the investigation, we reviewed your injury and illness log and determined it to be in compliance with the occupational health standard.

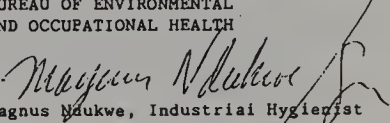
We reviewed your infectious control policies and procedures and found two violations:

- . We noted a violation of Michigan Occupational Health Standard Rule 4501(4)(b) because biohazard warning tags signifying the potential presence of infectious agents were not affixed to the linen bags.
- . We also noted a violation of Michigan Occupational Health Rule 3501(2) regarding personnel protective equipment. Your company did not provide puncture resistant gloves and aprons to employees sorting dirty hospital linens which contained needles or scalpels accidentally left by hospital personnel. Therefore, we recommend that you provide and assure the use of puncture resistant gloves and aprons made of "KevlarTM", heavy leather, or suitable high-strength material for all the employees sorting dirty hospital linens.

In summary, based on our observations, we determined violations of Michigan's Occupational Health Standards for General Industry on the date of the investigation and a citation is issued. Please note that you must sign the "Notification of Abatement" copy of the citation and return it to our office when the cited conditions are abated. We hope this information has been helpful to you, and please contact our office if you have questions regarding this report.

Very truly yours,

BUREAU OF ENVIRONMENTAL
AND OCCUPATIONAL HEALTH


Magnus Naukwe, Industrial Hygienist
Division of Occupational Health

MN/gw
Enclosures

cc: Mr. Gwyn Spruili, Union Representative
United Care Central Laundry
33000 Annapolis
Wayne, MI 48184

Michigan Department of Public Health
Division of Occupational Health

Citation and Notification of Penalty
Michigan Department of Public Health
Division of Occupational Health
3423 North Logan Street, P.O. Box 30195
Lansing, MI 48909

3. Issuance Date	4. Inspection Number
05/25/90	108047861
5. Reporting ID	6. CSHO ID
0552625	N2560
7. Optional Report No.	8. Page No.
	1 of 5

1. Type of Violation(s)	2. Citation Number
Other	01

The violation(s) described in this Citation are alleged to have occurred on or about the day the inspection was made unless otherwise indicated within the description given below.

10. Inspection Date(s):

3/21/90 - 3/21/90

11. Inspection Site:

4800 Rensy
Wayne, MI 48184

9. To:

United Care Central Laundry
and its successors
33000 Annapolis
Wayne, MI 48184

This Section
May Be
Detached
Before
Posting

Based on conditions found or information obtained at the location of inspection/investigation, it is alleged that you have violated Act 154, P.A. 1974, as amended. Alleged violations must be corrected by abatement date(s) noted below. In accordance with Sec. 33 and 35, Act 154, P.A. 1974, as amended, penalties are as indicated and shall be paid within 15 days after becoming a final order of the Board of Health and Safety Compliance and Appeals.

12. Item Number	14. Description	15. Date by Which Violation Must Be Abated	16. Penalty
13. Standard, Regulation or Section of the Act Violated			
1	29 CFR 1910.1200(e)(1) by authority of Section 14a(1) of Act 154, of the Public Acts of 1974, as amended: On March 21, 1990, the employer had not developed or implemented a written hazard communication program which describes how the criteria in 29 CFR 1910.1200(f), (g), and (h) will be met.	08/28/90	0.00

Abatement Required

Develop and implement a written hazard communication program which describes, as a minimum, how the requirements specified in paragraphs (f), (g), and (h) of the Federal Hazard Communication Standard will be met and which also includes a list of the hazardous chemicals known to be present plus other information as specified in 29 CFR 1910.1200(e)(1)(i), (ii), and (iii).

James J. Novak

17. Authorized Signature James J. Novak, Regional Supervisor (517) 335-8250

Last Pg

SEE REVERSE SIDE FOR POSTING INSTRUCTIONS AND PROCESSING PROCEDURES

PLEASE REFER TO THE INSPECTION NUMBER IN ADDITION TO
THE CITATION NUMBER IN DIRECTING ANY QUESTIONS,
OR CORRESPONDENCE

Total
Penalty
for This
Citation
Make Check or
Money Order
Payable to:
"STATE OF
MICHIGAN"
Indicate
Inspection
Number
on
Remittance

Michigan Department of Public Health
Division of Occupational Health

Citation and Notification of Penalty
Michigan Department of Public Health
Division of Occupational Health
3423 North Logan Street, P.O. Box 30195
Lansing, MI 48909

3. Issuance Date	4. Inspection Number
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7. Optional Report No.	8. Page No.
	2 of 5

1. Type of Violation(s)	2. Citation Number
Other	01

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10. Inspection Date(s):

3/21/90 - 3/21/90

11. Inspection Site:

4800 Renoy
Wayne, MI 48184

9. To:

United Care Central Laundry
and its successors
33000 Annapolis
Wayne, MI 48184

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Posting

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12. Item Number	14. Description	13. Date by Which Violation Must Be Abated	15. Penalty
3. Standard, Regulation or Section of the Act Violated			
408.1014a(6)(a), Act 154, Public Acts of 1974, as amended:		08/28/90	0.00
On March 21, 1990, the employer failed to provide employees with information and training on hazardous chemicals present in their workplace.			
Statement Required			
Provide employees with information and training on hazardous chemicals present in their workplace in accordance with 29 CFR 1910.1200(h).			

16. Authorized Signature: James J. Novak, Regional Supervisor

James J. Novak

18. Last Pg

SEE REVERSE SIDE FOR POSTING INSTRUCTIONS AND PROCESSING PROCEDURES

PLEASE REFER TO THE INSPECTION NUMBER IN ADDITION TO
THE CITATION NUMBER IN DIRECTING ANY QUESTIONS,
OR CORRESPONDENCE

Total
Penalty
for This
Citation
Issue Check or
Money Order
Payable to:
"STATE OF
MICHIGAN"
Indicates
Inspection
Number
on
Remittance

Michigan Department of Public Health
Division of Occupational Health

Citation and Notification of Penalty
Michigan Department of Public Health
Division of Occupational Health
3423 North Logan Street, P.O. Box 30195
Lansing, MI 48909

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4800 Renoy
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Based on conditions found or information obtained at the location of inspection/investigation, it is alleged that you have violated Act 154, P.A. 1974, as amended. Alleged violations must be corrected by abatement date(s) noted below. In accordance with Sec. 33 and 35, Act 154, P.A. 1974, as amended, penalties are as indicated and shall be paid within 15 days after becoming a final order of the Board of Health and Safety Compliance and Appeals.

12. Item Number	14. Description	15. Date by Which Violation Must Be Abated	16. Penalty
3	Rule 3502(11)(b) [Pursuant to Section 14, Act 154, Public Acts of 1974, as amended; Federal Reference 29 CFR 1910.134(a)(2)]: On March 21, 1990, the employer failed to establish and maintain a respiratory protective program which includes the requirements outlined in subsection 2 of Rule 3502.	08/28/90	0.00
Abatement Required			
Establish and maintain a respiratory protective program which includes at a minimum, the requirements outlined in subsection 2 of Rule 3502.			

17. Authorized Signature James J. Novak, Regional Supervisor

James J. Novak

18. Last Pg

SEE REVERSE SIDE FOR POSTING INSTRUCTIONS AND PROCESSING PROCEDURES

PLEASE REFER TO THE INSPECTION NUMBER IN ADDITION TO
THE CITATION NUMBER IN DIRECTING ANY QUESTIONS,
OR CORRESPONDENCE

Total
Penalty
for This
Citation
Make Check or
Money Order
Payable to:
"STATE OF
MICHIGAN"
Indicate
Inspection
Number
on
Remittance

Michigan Department of Public Health
Division of Occupational Health

Citation and Notification of Penalty
Michigan Department of Public Health
Division of Occupational Health
3423 North Logan Street, P.O. Box 30195
Lansing, MI 48909

3. Issuance Date 05/25/90	4. Inspection Number 108047861
5. Reporting ID 0552625	6. CSHO ID N2560
7. Optional Report No.	8. Page No. 4 of 5

1. Type of Violation(s) Other	2. Citation Number 01
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The violation(s) described in this Citation are alleged to have occurred on or about the day the inspection was made unless otherwise indicated within the description given below.

10. Inspection Date(s):

3/21/90 - 3/21/90

11. Inspection Site:

4800 Renoy
Wayne, MI 48184

9. To:

United Care Central Laundry
and its successors
33000 Annapolis
Wayne, MI 48184

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Based on conditions found or information obtained at the location of inspection/investigation, it is alleged that you have violated Act 154, P.A. 1974, as amended. Alleged violations must be corrected by abatement date(s) noted below. In accordance with Sec. 33 and 35, Act 154, P.A. 1974, as amended, penalties are as indicated and shall be paid within 15 days after becoming a final order of the Board of Health and Safety Compliance and Appeals.

12. Item Number	13. Standard, Regulation or Section of the Act Violated	14. Description	15. Date by Which Violation Must Be Abated	16. Penalties
4		Rule 4501(4)(b) [Pursuant to Section 14 of Act 154, P.A. of 1974, as amended. Federal Reference 29 CFR 1910.145 (e)(4)] On March 21, 1990, the employer failed to use biological hazard warnings (tags or signs) to signify the potential presence of biohazard, i.e. blood-borne infection agents in the laundry facility. A biological hazard warning (tag or sign) was not affixed to bags containing body fluid contaminated linens.	08/28/90	

Abatement Required

Provide biological hazard warnings (tags or signs) for the laundry facility and for the bags containing contaminated linens from the hospitals.

17. Authorized Signature: James J. Novak, Regional Supervisor

James J. Novak

Last

SEE REVERSE SIDE FOR POSTING INSTRUCTIONS AND PROCESSING PROCEDURES

PLEASE REFER TO THE INSPECTION NUMBER IN ADDITION TO
THE CITATION NUMBER IN DIRECTING ANY QUESTIONS,
OR CORRESPONDENCE

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Michigan Department of Public Health
Division of Occupational Health

Citation and Notification of Penalty
Michigan Department of Public Health
Division of Occupational Health
3423 North Logan Street, P.O. Box 30195
Lansing, MI 48909

3. Issuance Date	4. Inspection Number
05/25/90	108047861
5. Reporting ID	6. CSHO ID
0552625	N2560
7. Optional Report No.	8. Page No.
	5 of 5

1. Type of Violation(s)	2. Citation Number
Other	01

The violation(s) described in this Citation are alleged to have occurred on or about the day the inspection was made unless otherwise indicated within the description given below.

10. Inspection Date(s):

3/21/90 - 3/21/90

11. Inspection Site:

4800 Rensay
Wayne, MI 48184

9. To:

United Care Central Laundry
and its successors
33000 Annapolis
Wayne, MI 48184

This Section
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Detached
Before
Posting

Based on conditions found or information obtained at the location of inspection/investigation, it is alleged that you have violated Act 154, P.A. 1974, as amended. Alleged violations must be corrected by abatement date(s) noted below. In accordance with Sec. 33 and 35, Act 154, P.A. 1974, as amended, penalties are as indicated and shall be paid within 15 days after becoming a final order of the Board of Health and Safety Compliance and Appeals.

12. Item Number	14. Description	15. Date by Which Violation Must Be Abated	16. Penalty
13. Standard, Regulation or Section of the Act Violated			
5	Rule 3501 (2) [Pursuant to Section 14, Act 154, Public Acts of 1974, as amended; Federal Reference 29 CFR 1910.132(a)] On March 21, 1990, the employer failed to provide puncture resistant gloves and aprons to employees sorting dirty hospital linen which contained needles or scalpels accidentally left by hospital personnel.	Immediately Upon Receipt	0.00

Abatement Required

Provide and assure the use of puncture resistant gloves and aprons made of "Kevlar TH", heavy leather or suitable high-strength material for all employees sorting dirty hospital linens.

17. Authorized Signature **James J. Novak, Regional Supervisor** *James J. Novak* 18. \$ 0.00

SEE REVERSE SIDE FOR POSTING INSTRUCTIONS AND PROCESSING PROCEDURES

**PLEASE REFER TO THE INSPECTION NUMBER IN ADDITION TO
THE CITATION NUMBER IN DIRECTING ANY QUESTIONS,
OR CORRESPONDENCE**

52-372 76

Total
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Citation
Make Check or
Money Order
Payable to:
"STATE OF
MICHIGAN"
Indicate
Inspection
Number
on
Remittance

**SERVICE
EMPLOYEES**

INTERNATIONAL UNION, AFL-CIO, CLC



1313 L STREET N.W. • WASHINGTON, D.C. 20005 • (202) 898-3200

JOHN J. SWEENEY
INTERNATIONAL PRESIDENT

RICHARD W. CORDTZ
INTERNATIONAL SECRETARY-TREASURER

Testimony of

Bob Moore

President, Local 1199-E/DC

Service Employees International Union
AFL-CIO, CLC

Healthcare Worker Safety and Needlestick
Injuries

to the

House Committee on Small Business

Subcommittee on Regulation, Business Opportunities,
and Energy

February 7, 1992

My name is Bob Moore and I am president of Local 1199-E/DC of the Service Employees International Union. I am also a member of SEIU's Executive Board and on behalf of the 400,000 healthcare workers who are members of SEIU, I would like to thank Chairman Wyden and the other members of the Subcommittee for this opportunity to present our views on a matter of great concern.

You've heard testimony from my union brothers and sisters who are healthcare workers on the frontlines of the AIDS epidemic. They know first hand the hazards of HIV, hepatitis B and other bloodborne diseases and they also know first hand the inadequacy of the protection their employers provide. Some have been infected with HIV through preventable injuries. They join the growing numbers -- probably in the hundreds -- of those who have contracted HIV through exposure on the job. Although they're healthcare workers, they confront deadly hazards on the job just like coal miners and textile workers.

The first death of a healthcare worker who acquired AIDS on the job occurred last year. Joanne Ruiz, a registered nurse in California, became infected after a documented needlestick injury.

There is an epidemic of needlestick injuries in this country today -- upwards of one million every year. Since needles first came into use, healthcare workers have endured these injuries. The view of management has always been that such injuries are the fault of the worker who should accept them as part of the job. When workers express concern about needlesticks and the risk of infection, they are told to slow down and be more careful. Some hospitals threaten workers with disciplinary action, including dismissal, if they suffer too many needlesticks.

In the reality of today's healthcare industry, such advice is as absurd as it is dangerous. The stress among hospital workers is incredibly high because support staff is inadequate and vacancies among nursing staff remain at double-digit levels. In this environment, the use of inherently unsafe medical devices is a recipe for disaster. It's like telling workers to walk around a hole in the floor instead of repairing it.

Needlestick injuries are inadequately reported. We need to improve reporting and surveillance. Unfortunately, the spreading hysteria among healthcare management regarding healthcare workers infected with HIV and hepatitis B is likely to suppress further the reporting of these injuries. In response to misguided and unfounded recommendations by public-health authorities that infected healthcare workers endanger patients, many administrators have initiated a witch-hunt atmosphere. In this poisonous atmosphere, any worker who suffers a needlestick from a blood-contaminated needle is likely to conceal that fact because they fear for their livelihood.

This unfortunate situation is not likely to change until the Centers for Disease Control (CDC) communicates unequivocally to the public and the healthcare profession that infected healthcare workers do not pose a threat to patients. The CDC must communicate clearly that universal precautions and safer medical devices and procedures are the best protection for patients and workers alike. We urge the CDC to do so without further delay.

The occupational risk for hepatitis B has been known since the 1970's. In 1986, SEIU filed a petition with the Occupational Safety and Health Administration (OSHA) requesting action to protect workers from bloodborne infection. A final standard was not released until five years later, in December 1991. Inexcusable stalling by the Office of Management and Budget and the Department of Labor prevented OSHA from issuing a final standard until forced to do so by Congress.

Why is it only now that the risk of HIV faced by healthcare workers is becoming better understood by the public and policy makers? We believe that a one reason for this delay is the failure of the CDC to report adequately occupationally-acquired cases of AIDS. To this day, the three officially-acknowledged cases of occupationally-acquired AIDS remain buried under the reporting category called "Other/undetermined." We believe that there are many more and that it is time for CDC to make occupationally-acquired AIDS cases a separate reporting category.

We urge CDC to step up its efforts to report cases where occupational exposure of healthcare workers has resulted in HIV infection prior to the onset of fully-developed AIDS. Currently, CDC has reported only 36 cases of occupationally-acquired HIV infection. Better reporting and documentation is needed so that we can determine how these injuries occur so that they can be prevented. Needlestick injuries are discrete and identifiable events.

CDC led a major advance in infection control by recommending universal precautions in 1987. Changes in knowledge, technology, and practice require that CDC update its precautions as necessary. As we have heard today, unsafe medical devices play a major role in bloodborne infection. Therefore, CDC should immediately update its 1987 guidelines to address the need to prevent transmission of bloodborne diseases through the use of safer needle-bearing medical devices. In addition, CDC should recommend the modification of medical practices and procedures which are inherently unsafe. Universal precautions don't prevent needlestick injuries.

SEIU also urges the American Hospital Association and the Joint Commission on the Accreditation of Health Care Organizations to take similar steps to update their infection control guidelines.

Safer technology already exists and is available in the market. However, steps are needed to ensure that safer devices actually are safer and that unsafe designs are removed from the market. We recognize that neither CDC nor OSHA have the authority or expertise to regulate the design, intended use, and distribution of medical devices. This authority and expertise resides in the Food and Drug Administration (FDA). For this reason, SEIU petitioned FDA in April 1991 to develop performance safety standards for medical devices that contain needles along with other actions aimed at reducing the hazard to users posed by the design of these devices. Such a step is fully within the statutory power of the FDA to regulate the safety and effectiveness of medical devices. Furthermore, it is consistent with FDA's regulation of the quality of medical gloves to ensure that they protect users against bloodborne infection during normal use.

Furthermore, FDA action is needed because OSHA's bloodborne disease standard requires employers to control exposure by using engineering controls, that is, safer technology and equipment. Where medical devices are involved, it is up to FDA to regulate their safety and effectiveness.

In addition, SEIU urged FDA to improve its surveillance of injuries caused by needle-bearing medical devices. The recent controversy over silicone breast implants shows that FDA cannot afford to ignore devices which were essentially "grandfathered" when the Medical Device Amendments of 1976 were enacted.

SEIU applauds OSHA for issuing a final standard on exposure to bloodborne disease that contains the essential elements of a workplace protection strategy. We were shocked to learn that the American Dental Association, the American Health Care Association (which represents nursing homes) and the Home Health Services Association have initiated legal action to challenge the final rule. No OSHA standard in history has been so thoroughly examined or drawn so many comments and so much testimony. Their action is irresponsible and reveals them to be short-sighted employers putting profits before workplace safety. They're no different than the coal mine operators and textile-mill owners who fought so hard against workplace safety regulation in the past.

But it's even worse than that because the very same OSHA-mandated worker protections these organizations protest will also protect their patients. By this action they have surrendered any claim to represent health professionals who have sworn to put the health of their patients before all other concerns. We are confident that the court will treat their petitions with the contempt that they deserve.

SEIU believes that OSHA must undertake strong actions to ensure that the bloodborne

disease rule is adequately enforced. OSHA should implement a special emphasis program including extra training for inspectors and targeted inspections. Furthermore, OSHA needs to develop clear compliance guidelines on appropriate engineering controls including safer medical devices. Needlestick reporting on injury logs should receive special attention.

SEIU is encouraging local unions to meet with management to initiate needlestick injury prevention programs in the workplace. Such a program should have a written plan with definite targets for reductions in needlestick injuries and be carried out by a joint labor-management committee. This committee should review injury logs and make recommendations about changes in procedures and medical products. SEIU advocates worker representation on product evaluation committees. Broad worker participation is essential for an effective program of injury reduction.

The implementation of universal precautions and the changeover to safer medical devices will require changes in the practice and thinking of healthcare workers and administrators. That's why we need clear and consistent guidance from the three federal agencies with a responsibility in this area. CDC should update the 1987 Guidelines on Universal precautions to recommend safer devices and should also improve reporting of occupationally-acquired cases of HIV infection. OSHA should move aggressively to implement the new bloodborne disease standard especially with respect to engineering controls and needlestick injuries. Finally, FDA should move ahead on performance safety standards for medical devices with needles.

The healthcare workers you have heard from today, like their millions of colleagues around the country, will care for us when we need them -- without hesitating or discriminating. The real question before this subcommittee today is: Who will care for the healthcare worker?

Thank you.

Janine Jagger, M.P.H., Ph.D.

Associate Professor of Neurosurgery, University of Virginia

February 7, 1992

Testimony Before the Committee on Small Business

Subcommittee on Regulation, Business Opportunities, and Energy

The Honorable Ron Wyden, Chairman

**PREVENTABLE NEEDLESTICKS, PREVENTABLE HIV INFECTIONS,
PREVENTABLE DEATHS AMONG HEALTH CARE WORKERS**

Congressman Wyden, and committee members, I appreciate the opportunity to testify before this committee today and to shed light on an issue that has remained in the shadows far too long. I believe that the seriousness of the needlestick problem in the health care setting has been underestimated, and that health care workers, as a risk group for HIV, have been grossly neglected. I bring a message of both despair and of hope. Despair because the lives of tens of thousands of health care workers each year are unnecessarily devastated by occupational exposure to HIV and other pathogens, and the toll continues to mount, unabated. I am hopeful because we now have the technology to reduce the most frequent and serious of occupational blood exposures, needlesticks, to a small fraction of today's levels. Unfortunately, few health care workers have had the chance to benefit from these advances. I wish to stress the urgent need to employ all possible means to bring safer technology into the hands of health care workers as quickly as possible.

The number of health care workers affected by needlesticks is staggering. Current estimates are that about one million needlesticks occur in U.S. health care settings each year. Of those, 2% or about 20,000 needlesticks are likely to be contaminated by the AIDS virus, HIV. If available surveillance data are correct, we would then expect between 50 (1/400) and 80 (1/250) health care workers to become infected by HIV each year. We are all aware of the tragic consequences to those who are infected by HIV. However, the consequences to those who sustain HIV-contaminated needlesticks, even when infection does not occur, can also be devastating.

As many as 20,000 health care workers each year must endure months of uncertainty while waiting to learn if they have contracted HIV. The exposed individuals, many of whom are in their childbearing years, are compelled to take the same precautions as infected individuals until transmission can be ruled out. Many suffer devastating effects on their personal lives even though they have not contracted HIV. Some take an experimental course of AZT in hopes of reducing the probability of HIV infection. Although there is no indication, in practice, that AZT is effective for this purpose, there is a high likelihood of short-term side effects, and an unknown likelihood of long-term side effects.

The research that my colleagues and I conducted at the University of Virginia, has challenged the conventional, and I would add, incorrect, view that needlesticks are caused by the carelessness of health care workers. Our studies provide evidence that unsafe product design causes most needlesticks, and that relatively simple design changes can prevent them. For example,

we were astonished to learn that about 50% of needlesticks were caused by unnecessary needles, that is, needles used to access intravenous equipment, and not used to pierce the skin. This was not unique to our hospital. The use of such unnecessary needles is common practice, even today. Furthermore, an array of needle-less and shielded needle alternatives are available right now that could eliminate 50% of needlesticks tomorrow, if hospitals were adequately informed, and motivated.

For the remaining devices that require needles to pierce the skin, such as blood drawing devices, intravenous catheters and syringes, it is possible to provide a fixed barrier between the hands and the needle after use, that allows the hands to remain behind the needle as it is covered. Examples include a sliding sleeve feature that pushes forward after use and locks beyond the length of the needle, or a feature that allows the needle to be retracted backward after use into a rigid housing. Devices meeting these criteria are also available today. Our data tells us that the elimination of unnecessary needles, and the replacement of conventional unsafe needles with protective designs could result in a 90% reduction in needlesticks from hollow-bore needles. Theoretically, this level of prevention could be achieved now. What are the barriers that keep this technology out of the hands of health care workers?

The voices who speak out for safer medical devices for the protection of health care workers have been few and weak. The relevant government agencies, including the FDA, the CDC, and OSHA have been passive on this issue although medical device safety, infection control, and occupational safety fall squarely into their respective domains. The three agencies have demonstrated a recognition of this issue by sponsoring a joint conference on this topic, chaired by Dr. Murray Cohen of the CDC and scheduled for next August. Much more is needed. Policy commitment, program development, and research support are lacking.

Another barrier occurs at the hospital level where those making purchasing decisions are often administrators who are least likely to be informed about the benefits of safer products. And cost is sometimes cited as a barrier to purchasing new needle designs. I do not believe that safety will cost more in the long run. As safer devices begin to dominate in the marketplace, competition, and economy of scale will bring prices down. There are already examples of safer devices that cost less than their hazardous counterparts. The higher price of a safer device must also be weighed against the savings from reduced needlestick rates. The cost of a needlestick that does not result in disease transmission can vary from \$200 to \$1,000.

The response of industry to the need for improved technology is varied. Among the major medical device manufacturers, some have pursued the development of safer devices, for example, Baxter, Critikon, and Becton-Dickenson. Others have categorically ignored the safety concerns raised by their products, for example, Terumo, Sterling, and Wyeth. One troubling practice may obstruct the development of safer needles. Some companies acquire exclusive rights to key patents with the sole intent of preventing other companies from developing competing products. I am aware of such an instance in the field of safety needles. I believe, that when the technology has the potential to save lives, this practice should be illegal.

Finally, a major barrier to the acceptance of these new, and safer, devices is a lack of reliable documentation of their performance in hospitals. When the efficacy of needlestick preventing technology has been adequately demonstrated and communicated it will become increasingly difficult to justify the purchase of conventional needles. Support for this important research has not been available through federal funding channels. This remains a critical need.

The protection of health care workers from the hazard of needlesticks has been tragically neglected. Federal agencies, product manufacturers, and frontline health care workers must work together to get safer devices into the hands that need them. This transition cannot happen fast enough. Today alone, 2,400 health care workers sustained preventable needlesticks, and 50 of them plunged needlessly into crisis and uncertainty as they began their wait for HIV test results. Let us pursue every possible avenue to increase the availability of needlestick preventing technology. Let us put a halt to the needless tragedy in our health care workplace.

TESTIMONY

of the

AMERICAN NURSES ASSOCIATION,

AMERICAN ASSOCIATION OF CRITICAL-CARE NURSES,

ASSOCIATION OF NURSES IN AIDS CARE,

EMERGENCY NURSES ASSOCIATION

and

ASSOCIATION OF OPERATING ROOM NURSES

on

HAZARDS OF NEEDLE-STICK INJURIES

AND THE

ADOPTION OF SAFER MEDICAL DEVICE TECHNOLOGIES

by

Barbara Russell, MPH, RN

Before the

House Committee on Small Business

Subcommittee on Regulation, Business Opportunities, and Energy

February 7, 1992

Good morning, I am Barbara Russell, Chair of the American Nurses Association's (ANA) Task Force on AIDS. I have been a practicing nurse for over 30 years and have specialized in the prevention and control of infections for the last 18 years. I appreciate the opportunity to testify today representing ANA and its 53 state and territorial nurses associations, on behalf of the nation's two million registered nurses. I am also representing the American Association of Critical-Care Nurses (AACN), the Association of Operating Room Nurses (AORN), the Association of Nurses in AIDS Care (ANAC) and the Emergency Nurses Association (ENA). AACN's 70,000 nurse members provide care to critically ill patients. AORN's 47,000 registered nurses members provide care to patients in surgery. ANAC's 2000 members daily witness the devastating effects of HIV infection and AIDS. ENA's 21,000 nurse members provide care to patients in emergency settings. We commend the Committee for holding hearings on safe medical devices and needlestick injuries to health care workers, an issue of critical concern to nurses.

RISKS TO NURSES

Nurses constitute the largest number of health care workers in the industry, practicing nursing and providing health care in many settings. Nurses are on the frontlines in the health care arena, providing care to patients in critical care units, in operating rooms, in emergency departments, in nursing homes and in the community. We are patient advocates who, since the early days of the HIV/AIDS epidemic, have been at the forefront of movements to provide comprehensive compassionate care to those with AIDS and HIV-infection. Studies show that AIDS patients require almost double the amount of nursing time required by equally ill patients who do not have AIDS.

We believe reducing the risk of transmission of bloodborne diseases in health care settings, for the protection of patients and health care workers is of paramount concern. Nursing has advocated education and training regarding the use of universal precautions and infection control for our profession and the public. Nurses are keenly aware of the hazards of exposure to HIV and to hepatitis B which may result from contact with patients' blood or body fluids in a number of settings. Blood and body fluids are the field in which many nurses are immersed as they work. Although personal protective equipment, such as gowns, gloves, goggles and surgical caps are worn as needed and reduce the hazards of infection, the risk of exposure to bloodborne pathogens may still exist. The greatest risk of transmission of infectious agents to health care workers results from sharps which puncture the workers' skin.

IMPACT ON NURSES AND THEIR FAMILIES

Despite knowing that data shows a 0.4 percent chance of infection with HIV following a needlestick or cut with a sharp object, nurses are human and have fears like anyone else. The greatest fear of a nurse who has sustained a needlestick is that it will ultimately result in a potentially life threatening seroconversion. For nurses who have contact with the blood or body fluids of HIV or hepatitis B infected patients the months following the occupational exposure may be a nightmare.

These nurses must be counseled, their risk of infection evaluated and their fears addressed. They must take steps to protect themselves and their families. It means

adhering to safer sex practices and delaying family planning decisions. Something as simple as a fever must be assessed as a symptom of HIV or hepatitis B (HBV). Post exposure prevention medical treatment must be considered (such as hepatitis B immune globulin or booster shots, or other treatments for those exposed to HIV). Further, these nurses must be tested repeatedly for months, each test result awaited with great anxiety and strain to the nurses and their loved ones. The emotional toll can be very great.

The January 13, 1992 issue of *Nurse Week* includes a harrowing account of a nurse who was stuck by a needle while caring for a patient who has been an IV drug user for 20 years and nearly died of an AIDS-related illness. That nurse tells a story of fear, anxiety and nightmares. A single mother, she spends the late night hours calculating how old her son will be if she gets sick. She continues to be tested for HIV. The article is a painful testament to the emotional impact of needlesticks and is appended to our testimony. We ask that it be included in the record of this hearing.

Nurses who have acquired hepatitis B or HIV as a result of an occupational exposure report harrowing experiences which disrupt their lives leaving them financially and emotionally drained as well as ill. A Florida Nurses Association member, testifying before OSHA in 1989 stated: "My employer's speculation that my HBV came from my fiancée caused great embarrassment to us both...My life has been disrupted and permanently altered because of this illness. Aside from the physical effects of the disease, my family and I still suffer tremendous emotional and financial stress. During

the time I was unable to work I was totally without income. Because of the physical toll of hepatitis B, I was forced to take a less demanding job at much lower salary. In the space of a few months, I was financially ruined, my utilities were disconnected, and I am still trying to pay off collection agencies. My credit is ruined, and I still face medical and legal fees which may take years to pay. The home my children and I have lived in for the last seven years is on the market because I can no longer afford to maintain it."

In September, Congress heard testimony of Barbara Fassbinder, an Iowa nurse with HIV as a result of an occupational exposure. She testifies, "The workers' compensation system, my sole remedy in this case and a system that I had always assumed would take care of me in the event of such a catastrophe, falls far short of even my most modest expectations. It has been a source of endless frustration and disappointment. The responsibility is on the health care worker to prove infection in the workplace. My disability payments are based on a portion of my wages at the time of the accident. I happened to be working half-time at that time in 1986. Since there is no way a family of five can survive on 60 percent of half-time 1986 wages, we have had to rely on the Social Security System and the generosity of family to see us through. Health and life insurance not only for myself but for my husband and children who are not infected has become a nightmare."

The Centers for Disease Control have documented at least 40 cases of HIV seroconversions among health care workers. Of the 40 seroconversions 24 are fully

documented as occupationally injured and 16 are listed as likely. Seventeen of the forty are nurses; 36 were the result of needlesticks or other sharp objects. Needlestick injuries are a fact of life in the profession of nursing. It is an unfortunate, hazard of the profession. However, in the face of the AIDS epidemic, and the prevalence of hepatitis B, needlesticks have become far more anxiety inducing.

Immunization reduces the risk of contracting hepatitis B, however there is, as you know, no vaccine to protect against HIV. Unimmunized healthcare workers have a risk of 7-30 percent of acquiring hepatitis B, if such injuries occur from an antigen positive patient.

SAFER MEDICAL DEVICES

We urge immediate and ongoing research, development and evaluation of devices and equipment intended to reduce the risk of injury from sharps and of personal protective equipment designed to reduce exposure. In order to reduce the risk of exposure to bloodborne pathogens, we support the consistent and strict use of universal precautions; the availability of proven safety measures; the standardization of methods to ensure equipment is safe; and the continued evaluation and modification of work practices to ensure optimum safety in the workplace.

Although engineering controls are the first and best line of defense for worker protection, and are clearly the most important mechanisms for reducing risks of sharps injuries, education and training must go hand in hand with the use of such controls. We

know that when occupational safety and health standards have required engineering controls to address a hazard, they have been developed. Therefore, the technology exists in most hazardous work situations to control the risks of injuries from hazardous machinery or instruments. However, in health care, technological developments have not been emphasized sufficiently for several reasons including: the nature of medical and nursing practice; the equipment required; the reluctance of practitioners to adopt new equipment and methods which may alter procedures; their perceived effectiveness to health care workers. Additionally, such risks were not perceived as life-threatening. With the increased risk of serious injury and death from occupational exposure to bloodborne pathogens in health care settings, ANA urges increased research, development and availability in this area.

The use of protective medical devices based on research data and scientifically sound, effective practices, where feasible must be mandated. Data indicates that the largest group of exposures to blood involve needlesticks, a significant number of which could be prevented by the use of engineering controls such as automatic protective sheaths for needles. Such devices can significantly reduce the risk of needle sticks. However, we recognize that such devices may not be appropriate for all needles.

Therefore, continuous education and training to ensure safe handling of such equipment must be provided for students and in the workplace. Although needle and sharp disposal containers are widely available for use, not all hospitals provide them in convenient

locations. Some needlesticks occur after surgery or other procedures are completed and employees are performing clean-up procedures. Employees may be injured while manually transferring sharps from a bowl on the surgical table to an unsterile sharps container or disposable units conveniently located.

Certain design modifications of surgical instruments can minimize injuries. Disposable scalpels with acceptable "feel" and performance are needed. This would eliminate the necessity to assemble and disassemble a blade on a knife handle. Training programs for residents and surgeons on the use of electrical surgical units for cutting tissue could increase the number of surgeons adept in such practices, further reducing hazards.

We adamantly urge the modification of equipment and patient care practices to reduce the need for health care workers to handle sharp objects and large amounts of blood or blood-soaked items, and that for these situations, newly designed equipment be evaluated systematically to determine effectiveness during use.

FEDERAL REGULATIONS AND GUIDELINES

We believe that policies and guidelines to address the transmission of bloodborne disease in the workplace -- whether from patient to health care worker or health care worker to patient -- must be based on data from research on bloodborne disease transmission and established infection prevention and control practices.

Enforcement of and compliance with the OSHA bloodborne standard is an effective response to the risk of HIV transmission in health care facilities. It requires employers to implement universal precautions, to educate and train workers and to provide engineering controls and protective equipment to decrease employee risk of exposure to blood and body fluids and to injuries from needles and other sharps. Additionally, the cost of safer medical devices must not be so prohibitive as to have an adverse impact on patient care or staffing.

We also support the Centers for Disease Control's (CDC) position on infection control procedures including universal precautions and adequate education for healthcare workers and patients. The CDC recommendations emphasize educating health care workers and patients about proper infection control procedures and government established infection control standards.

We know that strict adherence to universal precautions and infection control procedures will limit the risk of transmission. We recognize the need for continued research and data collection on HIV transmission in the health care setting in order to increase the body of knowledge on which policy decisions are made.

Accurate reporting of adverse incidents involving exposure to bloodborne diseases can only be accomplished in an environment that acknowledges and has a full understanding of the critical nature of such information. Several agencies receive or require reporting

of information. CDC receives data regarding HIV exposure and AIDS cases. OSHA is to receive reports on occupational exposures to bloodborne diseases. FDA is asking for information whenever a device-user facility "receives or otherwise becomes aware of information that reasonably suggests that there is a probability that a device has caused or contributed" to the death, serious illness or serious injury to a patient at the facility. EPA oversees medical waste incidents. We acknowledge the need for all these reports; however, we must reiterate our concerns about confidentiality of person-specific information and data. This is especially important when information may be obtainable via freedom of information access.

Our organizations continue to work with CDC and the Occupational Safety and Health Administration (OSHA) to ensure development of effective policies and resolutions which encompasses education and prevention regarding bloodborne pathogens. Additionally, we urge Congress and the Federal and state agencies which have jurisdiction over devices: FDA - bloodborne diseases; CDC - patients; OSHA - workers EPA - environmental safety; to work together. The agencies must have appropriate funding to ensure timely regulatory actions, adequate qualified staff and resources and commitment and leadership in ensuring enforcement and compliance of relevant existing regulations. This is especially important in education and training regarding hazards, equipment and engineering control use and reporting of adverse incidents. Certainly agency action is also critical for product effectiveness, safety and cost evaluation. We are presently working with FDA as it implements the Safe Medical Devices Act and have

communicated our concerns regarding adverse incidents related to use of medical devices.

EDUCATION AND NATIONAL STANDARDS

As health care professionals, we understand that HIV transmission is reduced by strict adherence to universal precautions and other infection control practices, as well as by intensive education of consumers and health care professionals. Student health professional (who are not covered by OSHA regulations) must also be educated about disease and equipment management and use. OSHA has documented historically that inexperienced workers have more adverse occupational incidents.

All health care workers must follow universal precautions and established infection control procedures to reduce infection risks to patients and themselves. Appropriate use and disposal of needles and sharps, and safer medical devices are critical risk reduction strategies. In addition, universal precautions include the use of gloves, masks, eye protection and other barriers as needed for procedures that involve contact with blood and body fluids. Education of all health care workers about use of and enforcement of universal precautions in the workplace is critical to reducing the risk of transmission and must be ongoing.

CONCLUSION

We have undertaken educational programs on HIV disease and AIDS in the workplace setting and the OSHA standards for employee protection both nationally and with our individual state and regional bodies. We have pushed for better compliance and enforcement of CDC and OSHA standards. We support federal policies which would require annual education for all health care professionals to ensure that they are current on universal precautions. We strongly believe that these efforts must be coupled with engineering controls-the most effective line of defense for worker protection against sharps injuries.

Mr. Chairman, we support:

- immediate systematic research and evaluation studies of devices and equipment intended to reduce risk of injury from sharps and of personal protective equipment designed to reduce exposure risks;
- funding to support systematic studies;
- availability of proven safety devices;
- continued evaluation and modification of work practices to reduce the frequency of situations where exposure and/or injury risk to health care workers is greatest;
- and
- ongoing development and refinement of new safety devices.

We thank the Committee for the opportunity to testify today and look forward to working with you on the development of sound public policy to protect health care workers and health care consumers.

RSE WEEK

Southern California Edition • January 13, 1992

Schools seek financial aid

Valley Foundation and USC nursing

The nursing program at the University of Southern California (USC) is seeking financial aid from the Valley Foundation of Santa Clara County. The foundation was created when the Los Gatos Community Hospital and Rehabilitation Center was sold a few years ago, with the condition that profits from the sale would go to the newly created foundation to dole out grants to programs that serve the indigent, and for education.

ed in the work they want to says Virgil Parsons, DNSc, professor and chairperson of Jose State University's department of nursing.

or some schools, grants, gifts corporate funding come more than they do for others. Some

see results without significant effort, and others receive funds only as a result of considerable lobbying. For example, Parsons has received about \$500,000 over the last three years from the Valley Foundation of Santa Clara County. (The foundation was created when the Los Gatos Community Hospital and Rehabilitation Center was sold a few years ago, with the condition that profits from the sale would go to the newly created foundation to dole out grants to programs that serve the indigent, and for education.)

See "NURSING," page 7

JCAHO bans smoking in hospitals

By Christina Sponselli

As of Jan. 1, the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) issued regulations completely banning smoking in accredited hospitals—but it appears there are few cigarettes left to extinguish as the new rules are a rather belated reaction to a fully developed trend.

FIRST PERSON

Aftermath of a needlestick injury

The following story was not submitted anonymously; however, the writer feels anonymity is in the best interests of all concerned.

Life has not been the same since my needlestick injury a few months ago. I am an experienced nurse, and a careful one. I was also ignorant, and have since learned the importance of preparing for an injury before it happens. I hope my sharing this will help you, because if it has not occurred yet, eventually a job-related exposure to AIDS will happen to you or to one of your co-workers. This is my story.

The first day

I have just finished drawing blood on a patient. The winged IV set is designed to protect nurses from needlesticks, and I am attempting to slide the protective sheath over the needle. It doesn't budge. Instead, my fingers slide along the length of the needle and jerk back, with the needle embedded in my finger. One of the wings twists; the other breaks off completely.

My stomach turns queasy. The patient has been an IV drug user for 20 years and nearly died of an AIDS-related illness. It is very strange to see blood oozing inside my glove. I am transfixed by it, and can barely hear the patient asking if I've stuck myself. ...

The next half-hour is a blur of questions, consents, and more blood draws—mine, this time. My finger throbs and begins to bruise, probably because I have milked it so hard, and I feel cold and shaky. I try to focus on what the doctor tells me about the use of AZT prophylaxis in

See "TURNING," page 2

Researchers urge RNs to report patient assaults

By Mary Alice Cookson
While more research and better

researchers at the University of California, Los Angeles Neuro-



ST PERSON

urning a nightmare into "something positive"

nud from "AFTERMATH," page 1

stick injuries. No one really knows if AZT prevents seroconversion, he says, although the risk of becoming positive is low in cases like mine—roughly 0.3 per-
There may be side effects from the high dosage—

-pills? Will I lose my job if I become HIV-positive? Should I put off buying my first home? Thank God I already have a good long-term disability policy and decent life insurance.

The first week

I quickly find that I have to be brave for my co-workers. This incident has hit too close to home. I smile, I joke, I collect bugs, I assure them that I will take this one day at a time and that I will be OK. Then, feeling unusually energetic, I throw myself into my work.

When the nursing director, my supervisor and I meet with the product rep, he defends the needle's design. I tell him it is a cheap product that fell apart in my hands, and I show him the needle I used. Subtly, he attempts to put the blame for the incident on me, and I refuse to accept it.

(I become concerned, these days, when I hear of nurses eager to jump on the safety device bandwagon, ready to toss out the products they currently use. New and improved isn't necessarily better.)

Good news. The lab report shows I am protected against hepatitis B; I find the nurse who hounded me last year to get immunized, and I thank her. My baseline HIV test is negative.

Weeks two to five

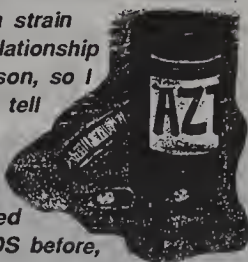
Dealing with this is harder than I thought.

Work is piling up. I no longer want to take care of patients or even answer the phone. Searing is my primary form of communication and nobody does anything good enough or fast enough. I have become the Nurse from Hell.

I am gaining a pound a week from junk food, and I flop onto the couch after work every night. In quiet moments, all I think about is AIDS.

The AZT bothers my stomach. My white count has dropped slightly, and I wonder if the AZT will cause prob-

The stress of keeping a secret has put a strain on my relationship with my son, so I decide to tell him what is going on. We have talked about AIDS before, but never like this.



As week six approaches, however, and the next HIV blood test is due, the emotional tightrope I walk begins to fray. I wake up crying one morning, unable to stop. The fear of testing HIV-positive is more than I can bear. The psychologist recommended by the Employee Assistance Program agrees to see me the next day because I am in "crisis."

Week six

Getting my blood drawn is very stressful, but I get through it. The nurse in occupational health brings the lab report to me as soon as she gets it.

I am still testing HIV-negative. The test will be repeated again at three months, six months and one year post-exposure.

I will go to weekly counseling, which is covered by workers' compensation.

A nurse colleague gives me a booklet, *If It Happens to You*, published by the California Nurses Association. I wish I'd had a copy earlier.

The booklet discusses what nurses need to know about occupational exposure in HIV and other blood-borne pathogens. It eases my mind to know that I am being treated under the current recommended guidelines.

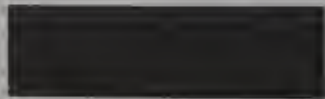
Weeks seven to 10

I guess I am getting used to all this; I no longer think about my HIV status all the time, and when I do, it doesn't send me into a tailspin. There are no plane crashes in my dreams now, no tears.

I am beginning to look at this experience as a way to learn more about myself and to grow; I see that I can turn it into something positive. I call on a friend when I need one and accept thoughts and feelings as they come. I'm finding how easy it is to simplify my life and make time for the important things.

Soon I will take advantage of my position where I work; nobody there knows needlestick injuries like I do, and my proposals for change will be listened to. Our policies are not bad, but they can be improved.

I will test again for HIV in two weeks, so this story is a "work in progress," as all of our lives are. 1992 will be an interesting year for me—and I hope a happy and healthy one for all of us. □



As week six approaches and the next HIV blood test is due, the emotional tightrope I walk begins to fray.

Four hours around the clock for six weeks—but the nurse says that if I were his sister, he would recommend take it. And one more thing: If I decide to take AZT, I will take the first dose within an hour of exposure, or the virus starts to replicate.

Afterward I find the nurse who was with me when I stuck it. We open the bottle of AZT and jiggle the blue and capsules around. Suddenly, I cry on my shoulder.

At home, my performance is brilliant. I help my son with his homework; I connect with my family over the phone; I go to a Boy Scout meeting. The pills stay hidden in my purse. At night, the nightmares return. I dream of frantically running down a dark, rain-soaked road, through thunder and lightning, trying to get to my son. As he is about to meet me a jet suddenly appears, cutting out of control from the sky, its engines flaming. We watch in terror as it crashes in flames below.

next day

Awake, angry and out of

control, I stay home from work and call a friend who used an AIDS needlestick last year. At her suggestion, I get a pill box that can be set to beep every four hours. She me that I will be in for a rough few months, but adds everything will be OK.

As I'm a worrier, and a single parent with a 12-year-old to raise, I calculate how old my son will be if I get sick. He will be a high school senior. College? Other questions spin through my consciousness. Do I keep hiding the

I am beginning to look at this experience as a way to learn more about myself and to grow; I see that I can turn it into something positive.



terms for me in the future, as there are on long-term studies on its effects. I have made the decision to take this drug, however, and I resolve to stick with it.

The stress of keeping a secret has put a strain on my relationship with my son, so I decide to tell him what is going on. We have talked about AIDS before, but never like this, and I am worried what his reaction will be.

He is concerned, but is reassured that the risk is small and that I am doing everything I can to take care of myself. The honesty puts us back on track.

Testimony before the
U.S. House of Representatives
Subcommittee on Regulation,
Business Opportunity and Energy

on

Needle-Stick Injuries to Healthcare Workers

February 7, 1992

Statement of

Joyce C. Lashof, MD
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&
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The American Public Health Association

on behalf of

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Mr. Chairman and distinguished members of the Subcommittee, my name is Dr. Joyce Lashof. I am the President of the American Public Health Association (APHA). APHA is a professional society founded in 1872, representing all disciplines and specialties of public health. As the world's oldest and largest multi-disciplinary society of public health professionals and community health leaders, APHA has throughout its 119-year history been in the forefront of countless efforts to protect and promote personal and public health. Since the outset of the human immunodeficiency virus (HIV) epidemic in the United States, the Association has led efforts to secure adequate resources and to assure that the formulation of policies and programs to deal with the epidemic are based upon scientific principles and sound public health practice.

Healthcare workers are at risk of acquiring hepatitis B virus, HIV, and other bloodborne infections through needlestick injuries and other occupational injuries which result in significant exposure to bodily fluids. The CDC estimates between 6,000 and 8,000 healthcare workers are infected with hepatitis B each year, resulting in 200-300 deaths annually. Nearly all of these are preventable through a program of vaccination of healthcare workers - advocated by APHA and now incorporated in OSHA regulations. There is a vaccine for hepatitis B, but currently there is not one for HIV.

Exposure to HIV is of particular concern to healthcare workers, because of the high mortality rate and lack of a curative treatment at this time. Recent studies have shown that the risk of acquiring HIV infection is approximately 0.4% following exposure through the skin to HIV-infected blood. This is

almost 100-fold less than the risk of hepatitis B infection after comparable exposure, but HIV is about 100 times as lethal.

There are no federal monitoring systems currently in place to track the extent of potential occupational exposures to bloodborne pathogens such as surveillance of needlestick injuries. Universal precaution guidelines were recommended by the Centers for Disease Control (CDC) in 1987. They recommend that all hospitals adopt an infection control policy by treating all bloodborne fluids as potentially infectious. However, CDC efforts to monitor occupational exposure to blood are limited. AIDS cases which cannot be classified into any of the standard AIDS risk categories are tracked and evaluated by CDC, but there isn't a separate occupational transmission category. There is a registry of persons known to have been occupationally exposed to HIV. However, there is no systematic monitoring of healthcare worker injuries involving blood, or surveillance of different types of medical devices to assess the degree of worker protection provided.

There is a general consensus that the number of healthcare workers infected with HIV through occupational exposures is greater than officially reported, although AIDS case reports suggest that there is no epidemic of illness through occupational injuries, comparable to that of hepatitis B in healthcare workers. APHA believes an important step would be the initiation by CDC of a formalized surveillance system of occupational injuries of healthcare workers in which exposure might occur. Collecting data on such factors as type of injury, type of device involved, and worker characteristics would allow for development of better worker protection strategies.

The Occupational Safety and Health Administration (OSHA) is currently in charge of enforcement of existing regulations concerning universal precaution guidelines, but does not track the extent of occupational exposures to HIV. The OSHA "Occupational Exposure to Bloodborne Pathogens" standard requires employers to implement procedures that include: use of gloves, masks, and other protective barriers to reduce exposure, care in the use and disposal of needles and other sharp instruments, training, and appropriate disinfection and sterilization of instruments and other reusable medical equipment. Employers also must develop written infection control plans to eliminate or minimize employee exposure. OSHA enforcement of this standard will include onsite inspections and the imposition of civil and criminal penalties for violators. APHA looks forward to the implementation of this standard and to its strong enforcement by OSHA.

The Food and Drug Administration (FDA) reviews medical devices and decides whether to give them FDA approval for marketing in the United States, but does not track the incidence of needlestick injuries or other occupational exposures to bloodborne pathogens. FDA plays an important role in preventing transmission of bloodborne pathogens in the occupational setting. In 1990, FDA promulgated regulations to improve the quality and reliability of medical gloves, but the design of needle-bearing devices has not been addressed by FDA thus far. Because the OSHA bloodborne pathogen standard does not define criteria for medical devices, employers are left to make their own interpretation of the performance safety criteria for needle-bearing devices.

Because APHA does not have the means to reach healthcare workers in the medical setting, we defer to medical groups on the issue of educational efforts to individual healthcare workers about needlestick injuries.

However, through our annual meeting, and policy participation at the national level we do engage in our own efforts to increase awareness about this issue. For example, at our 1991 annual meeting in Atlanta, 7 sessions dealt with this subject. APHA has a policy entitled "Occupational Transmission of Human Immunodeficiency Virus" that urges health care employers to educate employees about bloodborne disease and also urges employers to provide necessary equipment for workers to protect themselves from exposure.

In closing, because of the risks to healthcare workers of acquiring HIV and hepatitis B through needlestick and other occupational injuries, APHA supports strict adherence by employers to the OSHA bloodborne pathogens standard. We also recommend that CDC implement a surveillance system to track the extent of occupational exposures to bloodborne pathogens. It is also important that medical devices and equipment are evaluated to assess the degree of worker protection provided, and that proven safety devices are made available to healthcare workers. Finally, APHA believes that performance safety standards for medical devices (e.g., safer needle-bearing devices) need to be set.

Thank you.

House Committee on Small Business

Subcommittee on Regulation,
Business Opportunity, and Energy

Testimony on Needlestick Prevention Technology
Presented by Linda A. Chiarello, BS, RN, CIC
New York State Department of Health

February 7, 1992

New York State is the epicenter of the HIV/AIDS epidemic in the United States with over 42,000 cases of AIDS reported through December 31, 1991 and a projected 250,000 citizens infected with HIV. HIV-related hospitalizations accounted for 27,000 admissions in 1991 and on any day in New York City hospitals, over 1100 patients with an HIV/AIDS diagnosis are receiving care. It is therefore understandable that health-care workers in this state are very concerned about the safety of their work environment.

**Incidence of Occupational Exposure
and Disease Transmission**

The extent to which occupational exposure and transmission of bloodborne pathogens occurs in New York State is not reliably known. New York does not require the reporting of HIV infection and there is no centralized system to track occupational exposures to bloodborne pathogens. A few cases have been voluntarily reported but, in general, there is a reluctance to report occupational HIV seroconversions due to concerns of confidentiality, job discrimination, and other adverse consequences.

Hepatitis B infection is reportable but the investigation of outbreaks, rather than single cases, receives priority. There is therefore limited information on such cases among health-care workers.

In 1990, in an effort to gain some knowledge of these events, a voluntary survey was mailed to all New York State hospitals requesting information on the reported incidence of sharps-related injuries and subsequent bloodborne disease transmission between the years 1986 and 1989; 208 hospitals (80%) responded. Over 40,000 sharps-related injuries were reported during this period and resulted in 23 cases of hepatitis B and 3 cases of HIV seroconversion. Because Downstate hospitals (those in and around New York City) were less likely to respond to this survey, and underreporting of needlestick injuries, in general, is known to occur around 40% to 60% of the time, we believe this data underestimates the true degree of risk in New York State.

-2-

During 1991, data on sharps-related injuries was collected as part of a pilot study to determine the practicality and effectiveness of needlestick prevention devices. Incident data for 1990 and 1991 from six of ten participating institutions, revealed 2064 reported sharps-related injuries. Twenty-eight (1.2%) resulted in known exposure to hepatitis B and 156 (7.6%) were HIV exposures. Clearly, information of this magnitude underscores the urgency to address the issue of sharps-related injuries in our health care institutions and provides a framework for understanding the concerns of health-care workers.

New York State's Prevention Efforts

Until recently, New York State's bloodborne disease prevention efforts mirrored those of other states and federal agencies, namely issuing guidance documents on the methods and benefits of universal precautions and preventive practices, and encouraging hepatitis B vaccination. Regulations to implement the state's HIV Confidentiality Law in 1989 included a requirement for programs to prevent and manage occupational exposures to blood, which was intended to support existing and developing OSHA requirements. In reality, these regulations receive relatively little regulatory oversight in light of the overriding concern of monitoring and assuring quality of care. New York State must, therefore, rely on its state OSHA program and other oversight agencies to assist in the enforcement of occupational health programs for the prevention of bloodborne diseases.

In 1990, at the urging of New York State unions, legislation was enacted which gave the Commissioner of Health authority to establish ten pilot studies to evaluate the practicality and effectiveness of devices designed to prevent needlestick injury. This has provided the Department with an opportunity to gain information on strategies that can impact on this pervasive problem.

Impact of Prevention Technology

Although there are multiple devices which can cause SRIs, a certain few have been linked most frequently with occupational injuries. Our study, therefore, focused specifically on systems which utilize needles for intravenous (IV) delivery, administering medications by injection, blood withdrawal (phlebotomy), and inserting IV catheters. It is apparent from preliminary data analysis that the implementation of safer equipment has had an impact, particularly on injuries related to IV delivery systems. In five hospitals that implemented safer delivery systems hospitalwide either just before, or as part of, the pilot project, there was an overall reduction in SRIs of

-3-

and second half of 1991 in the three hospitals that implemented these systems as part of the pilot study, the impact is even more dramatic. Overall SRIs declined 30.8-55.9% and IV delivery-related injuries declined by 75%-93.8%.

With other devices, study designs precluded a hospitalwide impact analysis. However, with few exceptions, no injuries resulted with the use of the safer technology and, in one hospital, it appears that safer injection equipment decreased injuries by 30.4% but this needs to be verified.

Implications and Recommendations

This is encouraging data which speaks to the potential impact such technology can have. However, it must be tempered with economic reality. The incremental costs applied for by the institutions participating in this pilot project ranged from a low of 3.4% to a high of 1800%. The mean incremental cost, excluding the one device that was at the far end of the cost scale, was 196% which means that the cost of safer devices to replace the more hazardous needed equipment could cost institutions twice or more what they pay currently. For IV delivery devices, the incremental costs ranged from 2.5 to 6.5 times the the current market rate. While a decrease in injuries will offset the incremental costs, these savings are not always visibly apparent to administrators.

Other market barriers also impede implementation of a safer technology including withdrawal of products once they have been introduced and delays in acquiring or maintaining an adequate volume due to production problems. Such problems can discourage institutions that are trying to improve worker safety.

Factors which influence user acceptability must also be recognized and addressed. Devices which require major changes in technique or additional steps may limit adoption of a product. Devices which require that the safety mechanism be activated by the user will also impact on device acceptability and effectiveness.

These are challenges that can and must be addressed. To do so, however, requires a coordinated national effort that involves government agencies, the health care industry, unions representing workers, manufacturers and inventors, and workers themselves.

-4-

It is clear from our experience that devices with integrated safety features, the preferred option, must be evaluated clinically. Those involved with the New York State project believe there is a need for a central clearinghouse to establish design criteria for each type of product and to weed out those products that have no place in the armamentarium of devices to provide health care, and there are many. We believe this will require the FDA to assume a more prominent role in establishing standards for these products. There is also a need for economic incentives to both encourage research and development of a safer technology and its introduction into the health care setting.

Finally, I would like to acknowledge the efforts of so many in the manufacturing industry who are committed to developing and promoting a safer technology. We need their support and they ours. Together, we can make health care a safer environment in which to work.



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February 7, 1992

United States House of Representatives
Committee on Small Business
Subcommittee on Regulation,
Business Opportunities, and Energy

My name is Arthur Gianakos and I am the President and C.E.O. of North American Medical Products, Inc.

I would like to take this time to thank the Chairman of the Subcommittee for inviting me to address you on this very critical issue.

North American Medical Products was established in 1984 and introduced one of the first products to address cross-contamination in the anesthesia environment with a disposable fiber optic laryngoscope, which is used to help anesthesiologist and anesthesia nurses look into the airway to place an oxygen tube into a patient, either prior to surgery or during respiratory failure. Traditionally, stainless steel equipment is used with a lack of proper cleaning techniques and in many cases just rinsing a laryngoscope blade with plain water was the norm. Over the last few years the cleaning procedures have been improved but due to the cost and lack of manpower many hospitals still do not sterilize these products. Habits have been hard to break, and so we, as a company continue to face resistance to these systems which were designed to remove the concern of cross contamination.

Over the years, North American Medical Products has added new products to its line with the intent on providing quality, practical and economical products to the health care industry. In September 1990, we developed a needle protection device called the Safe-Site, which offers the hospitals a universal system which can be used to protect healthcare workers in approximately 70 -75% of the needle injection requirements. Thus, a comprehensive system which will make training easier and effective.

February 7, 1992

- 2 -

United States House of Representatives
Committee on Small Business
Subcommittee on Regulation,
Business Opportunities, and Energy

North American Medical Products

Additionally, we have developed the Safe-Site to eventually house the remaining 25 - 35% of the hospital needle stick requirements....but this will take money. As a small business pushing to grow larger, we fall into the proverbial cash-flow crunch. We have committed ourselves to addressing this issue because we believe that the everyday danger of accidental needle stick must be addressed not only for the immediate safety of the hospital and physician office staff but for the future of our young men and women who today think twice before committing to a medical profession due to the chance of contacting the H.I.V. Virus. Hospitals around the country are facing the difficult task of trying to retain existing personnel as well as attracting new ones.

With the Federal monitoring systems in place to determine the extent of accidental needle sticks I believe they are adequately in place. OSHA blood borne disease standard addresses many of the concerns relating to health care protection, however in the very near future a new standard must be made to allow for the benefit of new protective devices. An example being: When a needle is covered by a protective device and recapping of a needle is now made possible and there is no risk to the worker then OSHA must establish this fact in their standards procedures to hospitals to allow hospitals to recap needles with this type of protective device in place.

As a medical manufacturer, I have also been involved in the F.D.A. regulatory review process on medical devices and particularly with regard to sterile products. I have found their audits thorough and professional and their examiners to be fair and understanding, particularly to small businesses like ourselves. However, they require the same compliance from us as any other company and request our compliance to their recommendation within reasonable time frames.

Federal policies and procedures, specifically new OSHA standards will be a factor in forcing some hospitals to comply with the purchasing of needle protection devices and other sharp medical devices, however Federal agencies

February 7, 1992

- 3 -

United States House of Representatives
Committee on Small Business
Subcommittee on Regulation,
Business Opportunities, and Energy

North American Medical Products

to move in this direction.

It has come to my attention through one insurance company that accidental needle stick injuries have surpassed back injuries in claims made to workmans compensation. No doubt the A.I.D.S. scare has much to do with more nurses reporting these sticks. The insurance dollars that many hospitals could save on their premiums could easily surpass the cost of the medical devices. The reduction in cost of initially healing these healthcare workers and the follow-up treatment would generate even greater savings. Insurance companies must offer these incentive savings to these hospitals to move faster on these issues.

North American Medical Products originally was involved with anesthesia and anesthesia nurses who explained their concerns to me at various trade shows and what would be needed in the market place. As a result of these discussions, I proceeded to design and develop the Safe-Site which would allow for a universal protector as apposed to a single niche system. This would make training easier and reduce inventory costs to hospitals. We have accomplished this goal and have received the possitive feedback in both the U.S. and abroad.

The problem that we currently face with hospitals not moving quickly is cost or perceived cost. Many purchasing or administrative departments do not realize that in the course of a year the hospital will realize monetary savings as well as the positive influence on the psyche of their employees. There has been a growing number of devices for various niches which have entered the marketplace and many hospitals are trying to weed through the type they prefer. This has caused confusion and even delay in many cases, of finalizing decisions. These delays relate to cost, evaluations, review committees and period of time to finally go with something.

With regard to medical staff attitudes towards these new devices, there are many who feel an absolute need for these products and there are others

February 7, 1992

- 4 -

United States House of Representatives
 Committee on Small Business
 Subcommittee on Regulation,
 Business Opportunities, and Energy

North American Medical Products

protection has prompted many to accept change and adjust. I feel this trend will continue and new personnel will be trained properly on new systems that will become the standard.

Finally, the plight of the small business manufacturer must be addressed, particularly in this industry where new and exciting products are developed to help mankind. I have previously highlighted on this topic which addresses the financial aid needed to assist companies like ourselves, not in the form of loans which we already have and which usually are not enough and ultimately squeeze the company entrepreneur personally. What the Federal Government must do is provide Federal Grants for companies like ourselves who have invested in the design and development of these products and to use those funds for high production equipment, working capital for inventories, marketing expenses and any additional R & D for even more advanced and cost effective products. The benefit of high volume production equipment helps reduce hospital cost and allows companies like ourselves to meet the demands which will be needed in the age of protection.

The role of U.S. companies in this field of preventive devices is without question, a leading role world-wide. Historically our free enterprise system has allowed for new innovative thinking which has transcended into many innovative and ingenious products. Much of the world looks to the U.S. as a leader in the medical manufacturing field. As long as the H.I.V. epidemic increases, along with Hepatitis B & C as well as other infectious diseases there will be no doubt that a world standard for preventative devices will have to be established. Already we have been approached by several countries who have shown interest in marketing our product into their countries, primarily due to the ever growing concern for their healthcare workers.

It is estimated that just in the U.S. there are approximately 800,000 reported accidental needle sticks per year and growing. World wide the ratio would be staggering. The time has arrived where the U.S. Government must take a leadership role in a world prevention program.

Submitted to: Subcommittee on Regulation, Business
Opportunities and Energy

Submitted from: Kevin J. Seifert *K. J. Seifert*

Subject: Hearing on Needlestick Injuries to
Healthcare Workers and Adoption of Safer
Medical Devices by the Healthcare
Establishment

Date: February 7, 1992

I would like to thank the members of this committee and staff for their willingness to investigate the occupational hazard of needlestick injuries among healthcare workers. Needlestick injuries, which can transmit disease affect the health of medical workers, their families and patients, as well as the overall health and effectiveness of the U.S. health care system. I applaud any constructive intervention by this committee, Congress or appropriate federal agency that may lead to the eradication of one means of the spread of infectious diseases among the people of the United States and the world.

Over one million needlestick injuries are reported each year; if this seems alarming, consider the fact that most needlesticks go unreported. Every needlestick injury is a serious event because of the risk of exposure to hepatitis B and HIV, the virus that causes AIDS. A healthcare worker stuck by a needle contaminated with the hepatitis B virus has as much as a 30 percent chance of contracting hepatitis B. The CDC (Centers for Disease Control) estimates that 6000-8000 healthcare workers are infected with the hepatitis virus each year. One in four healthcare workers infected with hepatitis B develop jaundice or other acute symptoms. Every year, two to three hundred healthcare workers who contract hepatitis B from a needlestick die from the disease (or its related illnesses). A healthcare worker stuck by an HIV contaminated needle has a one in 250 chance of contracting HIV.

The general public is not well informed of the great risk to healthcare workers exposed to hepatitis B because AIDS related

stories receive more media attention. It is unfortunate that the death of 200-300 healthcare workers per year from hepatitis B is not given more significant coverage in the news media.

It is not realistic to expect monitoring systems on a federal basis to adequately detail the extent of needlestick injuries. Therefore we must rely on a hospital-by-hospital program of monitoring injury and demonstrating to employees, the severity of sticks by contaminated needles.

Every hospital, like every business, has a unique political atmosphere. Some institutions have a perceived fear that a needlestick is not an accident, but a sign of incompetence. Even though the hospital has not tried to create such an environment, the result is low reporting of needlesticks and other blood, body fluid and tissue exposures.

Several hospitals have developed new systems for reporting such accidents. San Francisco General has a 24 hour hot-line for needlesticks reporting. Trained counsellors on the hot-line help healthcare workers through the traumatic experience of injury, reporting and possible tests for infection. A healthcare worker who has just received a needlestick almost never knows the actual risk, because the status of a patient is generally not revealed to the healthcare worker due to universal precautions and patient confidentiality. Many cases are similar to these: A hospital employee is stuck by a needle in an overfilled sharps container, or a worker is stuck in the laundry room by a needle left in the bed sheets. These situations leave the worker with no

idea on whom the needle was actually used. This is a frightening experience, and only over a two to three month period does the worker fully understand the exposure they have faced. During this time they must ask themselves, should I abstain from sexual activities? Put my family through weeks of uncertainty? Withhold the information and try to live through this alone? Remember, this dilemma confronts the people who devote their lives to taking care of us more than one million times every year. I do not believe that in this day and age anyone should face this risk on a daily basis.

The CDC universal precautions guideline requires healthcare workers to treat all patients as if they are carriers of every possible health risk and use proper protection. This guideline is essential because one may not know who is and who is not a carrier of a potentially deadly virus like hepatitis B or AIDS. It does have one shortcoming however: human nature. It is natural that no one would believe that a 72 year old grandmother could have HIV. Yet, in reality she may have received an infected blood transfusion or a tainted dialysis procedure and actually be a carrier. Preconceptions healthcare workers have about a patient (whether one may or may not be a health risk) are the weak point of this guideline. With time, and the understanding that all patients must be treated with proper protection, this guideline will grow to become second nature. That understanding is growing daily.

OSHA's blood borne standard is taking universal precautions to the next level. It makes the employer responsible (by monetary

fine) for employees' actions. It also states that the employer must consider exposure, engineering and work practice controls. These controls are important because they dictate the actions to take when an employee faces possible exposures, and proper procedure to follow when one has been exposed.

If OSHA now uses this standard to levy fines when appropriate, this standard could become reality.

OSHA's mandatory "free of charge" hepatitis B vaccination program for workers who have contact with hepatitis B is a step in the right direction.

There has been a great deal of discussion amongst health care organizations about the FDA regulatory review process on medical devices. With the workload and expectations placed on the FDA for approvals within reasonable time frames, I do not believe that we can expect the FDA to review devices with the user's exposure in mind without an increase of staff and financial support. As in other industries, often appropriate non-profit organizations are sanctioned to examine and review the user safety aspect of products for the consumers. In the medical field, ECRI (Emergency Care Research Institute) is such an organization. It is a non-profit agency which has done a complete review of safety medical devices and continues to update its reviews with newly released products. ECRI tends to be direct, and does not hesitate to point out the flaws it finds in products.

It is important to realize that the technology of safer medical devices, like any evolving product, is still maturing.

Many of the products being marketed are first generation, soon to be extinct. I believe that the best way to assess a device is to ask: does it require manipulation once it is removed from the patient, does it require behavior change, and is the new device safer than the original needles? Many first generation devices that require exposed manipulation are not safer than ordinary needles; and in many cases create new needlestick hazards. I applaud the efforts of any agency to become involved in the review of such devices. I would like to remind you that hospital products, like all retail products, are put to test by the consumer. Those that are clearly superior rise and those that are not, fall.

As a small manufacturer, there are some governmental factors that inhibit the introduction of new technologies.

Many investors are hesitant to support the future of our country's economic growth, because even if they are fortunate enough to pick a start-up company that does become successful they lose about 40% of the income to taxes. When you consider the odds of success vs failure, and then add the significant loss to taxes, it is no wonder that many of our new and innovative ideas do not gain financial support or make it to market. The complete removal of the capital gains tax is not necessary. A significant reduction of capital gains tax and an incentive program for investors that support start-up and small companies would be more appropriate. It is time we gave a proper reward to those who take the risks that result in gains for us all. If this committee were to establish an incentive program in which an investor would

receive some type of tax incentive to invest in start-up or small businesses, you would see an immediate growth in the corporations of the future. This type of program would help the American investor to stimulate the growth of our economy. Without it, we will continue to see fewer and fewer new innovative products from new American companies.

Education was the first line of attack used by hospitals to reduce the risk of needlesticks, but it did not solve the problem alone. At this time attention is being paid to the use of safer devices as a means to stop needlesticks.

Bio-Plexus has developed a unique safety device, a needle that is self-blunting. Our first product based on this design is a needle which is used for drawing blood. The concept and operation of this needle are quite simple. When a Bio-Plexus Punctur-Guard needle is removed from a patient, it no longer has an exposed sharp point. When the device is used to draw blood or give an injection, the natural action of the user advances an inner blunted needle just past the point of the outer sharp needle and locks it into place. In this way, the needle is rendered safe before being removed from the patient, and the healthcare worker's risk of exposure to disease is virtually eliminated. The National Phlebotomy Association, which is the largest and oldest phlebotomy association in the nation, has endorsed the Punctur-Guard Phlebotomy needle. This is very impressive when one considers that no other device has ever been endorsed by this organization. Our next product will be in IV vein access catheter. This product is

greatly anticipated by the American Medical Association, hospitals and home health care nurses.

Many hospitals are in the process of implementing the use of new, safer devices, though most are not. The sole reason for the lack of action on the part of these institutions is cost. Hospital administrations require Infection Control nurses and safety committees to cost-justify needlestick protection measures. But, is this a realistic justification? In any other high risk occupation; no one would be asked to justify the cost of safety goggles compared to that of losing an eye. The risk from a needlestick is not to sight but to life; and the use of the Bio-Plexus Punctur-Guard virtually eliminates that risk, at an added cost of less than a dime. We need to put aside the cost justification question when over 200 healthcare workers are dying from hepatitis B each year, and when risk of exposure to HIV is growing constantly. It is a sad commentary on our society that we care more for our bottom line than the safety of those who take care of us.

As with any new product, when the market truly demands and supports these new innovative devices, the large corporations will take notice and start making competitive products that are not just first generation concepts. This interplay will support even more cost effective products. But, if we do not support the newer company's products and force the large corporations to react, these corporations will stay with current technology, because profitability is greater without change.

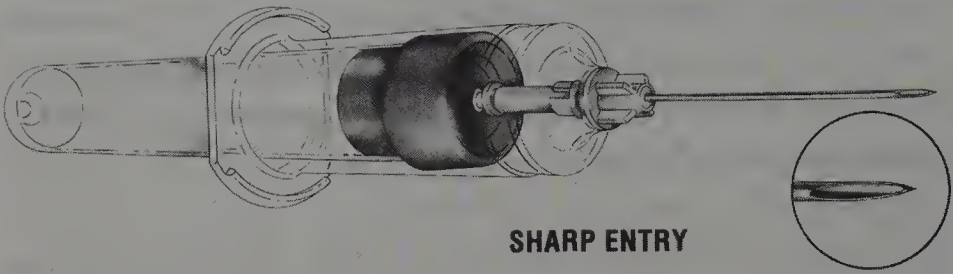
New technology aside, there is one area that does clearly

require more education and mandatory certification. That is phlebotomy, the act of drawing blood. This invasive procedure is performed by personnel who, in many hospitals, receive inadequate (if any) training prior to drawing blood on a patient. This training is currently available through certifying organizations like the National Phlebotomy Association. Yet some hospitals do not have in place any certification requirements. This puts patients and phlebotomists at unnecessary risk. Simply put, phlebotomists who are not certified are putting themselves and patients at greater risk because they have not been taught the procedures to protect themselves from needlesticks. I urge this committee and other health care committees to mandate certification for the invasive procedure of phlebotomy.

Lastly, I would like to comment about the actual user of these safer medical devices. It is natural to resist change, especially when having to adjust to on-the-job tasks. I agree, and understand, that some new devices require an exorbitant amount of manipulation and change in behavior. Many safer devices, however, do not. I have heard user resistance in many forms regarding many different companies products. But the truth remains that there are affordable safer medical devices that work with little or no manipulation or behavior change. Managers of healthcare workers must remember that there is no product or service of any type, including: cars, clothes, restaurants and medical devices, that everyone will approve of. They should look, listen and then conclude whether the comments concerning a product being tested are

resistance only to change, or to a truly unacceptable product.

The safety products of tomorrow are ones that do not require the healthcare worker to undergo significant behavior changes. They are devices that are engineered smarter and result in making the healthcare worker's job safer.



PRESENTATION DISPLAY SHOWING SELF-BLUNTING SYRINGE
SUBMITTED BY KEVIN SEIFERT
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WILLIAM JOHNSON

Statement
of the
American Hospital Association
before the
Subcommittee on Regulation, Business Opportunities, and Energy
Committee on Small Business
U.S. House of Representatives
on
Needlestick Injuries and
the Adoption of Safer Medical Device Technologies

February 7, 1992

SUMMARY

Strict adherence to universal precautions, which require the use of a barrier, such as gloves, gowns, or masks or protective eyewear, minimizes the risks of most exposures to bloodborne pathogens faced by health care workers. Universal precautions alone, however, cannot prevent certain accidental exposures, particularly injuries that result from needlesticks and other sharp instruments. Despite the relatively low risk of transmission of HIV, the devastating consequences of acquiring HIV infection heightens the importance of reducing sharps injuries.

AHA and its member hospitals strongly support the development and implementation of effective new technologies to reduce such injuries, but many available new technologies never have been tested for safety or efficacy in a clinical setting. The risk of exposure from sharps injuries is very real, but the blind adoption of every new device that hits the market would likely not serve workers or managers of health care budgets. The most constructive role that Congress and various Executive branch agencies can play is to lend support for increased evaluation efforts, including assessments of the safety and cost-effectiveness of particular devices, and stronger coordination of efforts to disseminate the results of such evaluations.

Introduction

Mr. Chairman and members of the committee, my name is William Johnson, CEO of the University of New Mexico Hospital in Albuquerque, New Mexico. I am here today on behalf of the American Hospital Association (AHA) and its more than 5,300 member institutions to address the hazards posed to health care workers by needlestick injuries and the adoption of safer medical device technologies by health care institutions.

As chair of the AHA's current ad hoc committee on HIV infection as well as chairman of the 1987-88 committee that developed AHA's initial policies related to HIV, I can speak about the longstanding commitment of AHA and its member institutions to enhancing worker safety. We have long worked to enhance worker safety by expanding efforts to reduce the risk of occupational injuries to health care workers, including the use of effective new technologies, thereby minimizing their risk of exposure to various bloodborne pathogens (e.g., HIV infection, hepatitis B virus). The risk of exposure from sharps injuries is very real, but the blind adoption of every new device that hits the market would likely not serve workers or managers of health care budgets.

Risk of Occupational Exposure is a Real Concern

Strict adherence to universal precautions, as recommended by the Centers for Disease Control (CDC) and mandated by the Occupational Health and Safety

Administration (OSHA), minimizes the risks of most exposures to bloodborne pathogens faced by both health care workers and patients. Universal precautions require the use of a barrier, such as gloves, gowns, or masks or protective eyewear, when exposure to blood and other potentially infectious body fluids is anticipated. But universal precautions are of limited value in preventing certain accidental exposures, particularly injuries that result from needlesticks and other sharp instruments. Sharp instruments such as needles may penetrate barriers and potentially expose health care workers to infected blood or body fluids.

Health care workers who sustain accidental injuries from sharps such as needlesticks face a small, yet nonetheless, real risk of acquiring HIV infection. The CDC estimates that the risk of acquiring HIV infection following a percutaneous exposure to infected blood (i.e., a needlestick or a puncture from a sharp object) is approximately 0.3 percent for each exposure. As of October 31, 1991, CDC was aware of 28 health care workers who had tested positive for HIV antibodies following a well-documented occupational exposure to infected blood. The majority of these exposures occurred after percutaneous injuries. An additional 18 health care workers are thought to have acquired HIV infection through occupational exposure but documentation for these cases is less clear. Despite the relatively low risk of transmission and the small number of documented cases of occupationally acquired infection, the devastating consequences of acquiring HIV infection heightens the importance of reducing sharps injuries.

Injury Prevention is Paramount Concern for Hospitals

Although no work environment can be made completely hazard free, the AHA and its member institutions are committed to protecting health care workers and patients from injuries that potentially expose them to various bloodborne infections, including HIV. AHA has been in the forefront of efforts to promote worker safety, developing print and video materials to educate health care employers and employees about the occupational risks of acquiring bloodborne infections and ways to reduce those risks.

/AHA developed recommendations for its member hospitals on managing HIV infection in the institutional setting as early as 1983. We have regularly updated those recommendations, first in 1986 when we urged adherence to blood and body fluid precautions and again in 1988 when we issued a broad set of policy recommendations.

/First established in 1940s, AHA's Technical Panel on Infections within Hospitals has frequently issued technical guidance to hospitals on HIV and HBV transmission issues.

/In 1987, we produced a teleconference entitled "AIDS: Protecting Hospital Employees."

/"Working Together: Needlestick Prevention" in which AHA combined a video format with educational print material was developed in 1989.

/In 1989, AHA emphasized the importance of worker safety education and the development of effective safety devices in reducing the risks of needlestick injuries in newspaper editorials.

/In 1990, AHA created "Universal Precautions: Multimedia Building Blocks for Prevention and Compliance Training" which combines video, slides, and print material.

/AHA has been involved in a 1990 national effort coordinated by the Service Employees International Union (SEIU) to develop effective strategies for preventing needlestick injuries.

/AHA staff continue to serve as faculty at various worker protection training programs and seminars, addressing occupational risks of bloodborne pathogens and strategies for risk reduction such as the use of universal precautions and sharps safety.

We also have worked closely with the Occupational Health and Safety Administration (OSHA) to develop appropriate and effective standards for the prevention of occupational transmission of bloodborne pathogens. Final regulations promulgated in December 1991 by the Occupational Health and Safety Administration (OSHA) require hospitals to adopt engineering controls (e.g.,

safety control devices such as puncture-resistant containers for used sharps) as their first line of defense in eliminating or minimizing employee exposure to potentially infectious materials. Rather than mandating specific technologies, these regulations allow hospitals to choose the most appropriate and effective safety control devices for their specific institutional needs. Ensuring continued compliance with the OSHA regulations to ensure worker safety is a paramount concern to AHA and its member hospitals.

AHA believes that it is inappropriate for an organization such as ours to endorse particular commercial products. We do, however, frequently communicate with member hospitals about available technologies to prevent needlestick injuries and methods to evaluate and select appropriate and effective safety devices. Hospitals then evaluate specific safety technologies and choose the most appropriate ones for their own use, often through institutional committees composed of infection control experts, clinical staff, labor representatives and management.

Lack of Data on Device Effectiveness Hinders Institutional Adoption of Technology

Hospitals are faced with a plethora of new products designed to prevent needlestick injuries. Unfortunately, the reality is that many of these products never have been clinically tested for safety or efficacy. Currently, hospital occupational health experts are essentially "on their own" when it comes to selecting safer products.

We are encouraged that some studies of the clinical impact of various safety devices to prevent needlestick injuries are currently underway. The State of New York launched a multi-hospital study of the impact of a variety of needle-safety devices last year. Under this project, the state provides funding for the costs of devices being studied when their costs exceed those of standard devices traditionally used by participating hospitals. In addition, the New York City Health and Hospitals Corporation is undertaking a separate major evaluation of a variety of safety devices, addressing such issues as ease of use, training requirements, and whether users would be required to adopt new techniques when utilizing the devices in clinical treatment. Data from such studies will be useful to all institutions when selecting safety devices appropriate to their specific institutional needs which are therapeutically effective, effectively enhance worker safety when used in specific clinical settings, and are not cost-prohibitive.

AHA has long advocated for the development and implementation of new technologies that are effective in reducing the risk of on-the-job injuries to health care workers. Not enough is being done, however, to provide health care institutions with sound evaluative information. In the current health care economic environment, it would be imprudent to adopt costly technologies that are either ineffective or actually increase worker injuries because they are poorly designed. The most constructive role that Congress and various Executive branch agencies can play is not to mandate use of new technologies, but to lend support for increased evaluation efforts, including those assessing the safety and cost-effectiveness of particular devices, and stronger coordination of efforts to disseminate the results of such evaluations to health care workers and practitioners.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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STATEMENT OF

DAVID M. BELL, M.D.

CHIEF, HIV INFECTIONS BRANCH

HOSPITAL INFECTIONS PROGRAM

NATIONAL CENTER FOR INFECTIOUS DISEASES

CENTERS FOR DISEASE CONTROL

PUBLIC HEALTH SERVICE

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

BEFORE THE

SUBCOMMITTEE ON REGULATION, BUSINESS OPPORTUNITIES AND ENERGY

COMMITTEE ON SMALL BUSINESS

U.S. HOUSE OF REPRESENTATIVES

FEBRUARY 7, 1992

Good afternoon. I am Dr. David M. Bell, Chief, HIV Infections Branch, Hospital Infections Program, National Center for Infectious Diseases, Centers for Disease Control. Accompanying me is Dr. Robert J. Mullan, Medical Officer, HIV Activity, National Institute for Occupational Safety and Health, Centers for Disease Control. We appreciate this opportunity to present information on the hazards of needlestick injuries in health-care workers and on CDC's activities to prevent these injuries.

Many health-care workers are potentially at risk for infection with bloodborne pathogens due to exposure to infected blood. The type of blood exposure having the greatest risk of infection transmission is percutaneous exposure, that is, a needlestick or cut with a sharp object contaminated with infected blood. Risk reduction strategies include designing and evaluating improved medical and dental devices and other engineering controls, work practices, and personal protective equipment, as well as delivering educational programs, conducting surveillance and risk assessments, and evaluating compliance with guidelines and regulations.

Much of the current concern regarding percutaneous injuries has been prompted by reports of occupationally acquired HIV infection among health-care workers. However, there are other recognized

bloodborne pathogens, for example, hepatitis B and C viruses, which pose occupational risk as well. Even if a percutaneous injury does not result in transmission of infection, the injury can be painful and lead to loss of work time. Injured workers require medical evaluation and some may be treated with injections or potentially toxic drugs to try to prevent infection. Also, injured workers and their families may be subjected to considerable stress during follow-up periods lasting up to six months or more as they wait for the results of tests for infection.

In order to assess the risk of HIV infection in health-care workers and the efficacy of preventive measures, CDC conducts a variety of surveillance projects and epidemiologic and laboratory investigations. Data collected are used to develop and update CDC guidelines for the protection of health-care workers.

Surveillance of health-care workers with AIDS, conducted as a component of the CDC National AIDS Case Surveillance System, has demonstrated that health-care workers are not overrepresented among reported cases of AIDS. As of December 31, 1991, health-care workers represent 4.8% of the 160,000 cases of AIDS in adults from whom occupational information is available, whereas, approximately 5.7% of the U.S. labor force is employed in health services. Of the 7,652 health-care workers with AIDS, 3 seroconverted (i.e., tested negative for HIV then subsequently

tested positive) in association with a documented occupational exposure to HIV-infected blood, and subsequently developed AIDS. Of the remaining 7,649, 94% fall within one or more well-recognized, non-occupational transmission categories, and 6% have an undetermined risk.

Data on health-care workers with AIDS are disseminated in a variety of oral presentations and publications, including CDC's monthly HIV/AIDS surveillance report. This report specifies the number of cases reported to have developed AIDS after exposure in health-care settings, as documented by seroconversion or other laboratory studies. However, AIDS surveillance data are collected under an assurance of confidentiality which stipulates that the data will not be used in a manner which would permit identification of any individual. In the monthly report, AIDS case data are tabulated by risk, sex, and race. Since there are a relatively small number of cases due to exposure in health-care settings, these cases are grouped within the larger "Other/undetermined" risk category in order to avoid compromising their confidentiality during these cross-tabulations. A detailed review of CDC surveillance data on health-care workers with AIDS, including how the data are collected and classified, was published in the December 25, 1991 issue of the Journal of the American Medical Association. With the subcommittee's approval, I would like to submit this published report for the record.

CDC also conducts surveillance of cases of occupationally acquired HIV infection, regardless of whether the worker developed AIDS. As of December 31, 1991, CDC had received reports from state and local health departments of 29 workers in the United States who had seroconversions to HIV after a documented occupational exposure; 3 of these health-care workers developed AIDS and are included in the AIDS case data which I just mentioned. Twenty-seven workers were exposed to HIV-infected blood, one worker was exposed to concentrated virus, and one worker was exposed to an unknown fluid. Of the 29 health care workers, 24 had percutaneous exposures, 4 mucocutaneous (e.g., eyes, nose, mouth or skin), and one health-care worker had both a percutaneous and a mucocutaneous exposure. In addition to the 29 health-care workers with documented seroconversion, 18 other cases of health-care workers with HIV infection (without AIDS) were reported in this surveillance project; these 18 workers did not report other risk factors for HIV infection, but blood specimens were not available to document transmission of infection after specific occupational exposure.

Information on the risk of HIV infection after a single percutaneous exposure to HIV-infected blood is available from CDC surveillance of health-care workers with occupational exposures to HIV-infected blood; 260 hospitals currently participate in this project. As of December 31, 1991, 1644

health-care workers were tested for HIV antibody at least 6 months after exposure; 3 (0.21 percent) of 1447 workers with percutaneous injuries seroconverted to HIV. None of the 197 health-care workers with mucocutaneous exposures seroconverted in this study. Similar results have been obtained by other investigators in the United States and abroad. These data document that health-care workers are potentially at risk for occupationally acquiring HIV infection due to exposure to infected blood and that the major risk is due to percutaneous exposures.

Additional ongoing CDC activities to assess occupational risk of HIV infection in health-care workers, the extent of compliance with precautions recommended by CDC and others, and the efficacy of these precautions include monitoring HIV seroprevalence in patients in selected hospitals and clinics, conducting HIV seroprevalence surveys in groups of health-care workers, determining the frequency and circumstances of contact with blood among health-care workers, assessing compliance with "universal precautions" in various categories of hospital workers, and assessing educational and motivational techniques to enhance health-care worker compliance with prevention practices. An up-to-date assessment of risks and risk reduction strategies was published by CDC in the American Journal of Medicine in 1991 (Am J Med 1991;91(suppl 3B): pages 294S and 297S). With the

subcommittee's approval, I will submit this document for the record.

Hepatitis B virus is approximately 100 times more transmissible than HIV after a needlestick exposure to infected blood (30% vs. 0.3% respectively). In 1990, hepatitis B virus was estimated to cause approximately 6,500 occupationally acquired infections among health-care workers in the United States, based on reported cases of hepatitis B nationwide (corrected for underreporting and asymptomatic infections) and investigations of cases in "sentinel" counties. The proportion of these cases due to percutaneous injury is unknown. The occupational risk of hepatitis B infection has been documented to be highest in workers having the most opportunities for blood exposure. However, for most believed to have occupationally acquired hepatitis B infection, a specific exposure to infected blood was not documented. Unlike HIV, hepatitis B virus is present in blood in high concentrations and remains viable in the environment for extended periods of time. It is believed that many health-care workers acquire hepatitis B infection through unrecognized exposures to blood, perhaps through small breaks in skin or by mucous membrane contact. Fortunately, most hepatitis B infections are now preventable with appropriate use of vaccine.

Reliable data on the frequency of percutaneous injuries in

health-care workers are limited. Hospital employee health service records have historically underestimated the true injury rate, due to underreporting. In studies conducted in 1983, Marguerite Jackson, R.N., M.S., at the University of California at San Diego and Bruce Hamory, M.D., at the University of Missouri at Columbia each found that 40% of needlesticks among employees surveyed in their hospitals were not reported to the employee health service. Underreporting is believed to be even higher among health-care workers who are not employees of the hospital, such as physicians. Some experts believe that the extent of underreporting may be declining, as health-care workers develop an increased appreciation of the hazards posed by bloodborne pathogens and recognize the need to document their exposure in order to receive follow up medical evaluation and treatment and to be eligible for compensation should they become infected. Other experts fear that many injuries are still not reported, due not only to the inconvenience of making a report, but also due to fear of being held responsible for the injury, or fear of potential discrimination or loss of employment if the worker should acquire HIV infection.

The most detailed and reliable data on needlesticks and other percutaneous injuries are derived from prospective studies. In studies conducted by CDC, surgical and obstetrical personnel and hospital emergency department workers have been observed while

performing procedures in order to ascertain the nature and frequency of blood exposures. CDC-sponsored studies of percutaneous injuries among nurses on medical wards, among obstetrical personnel, and among prehospital care providers are in progress.

Results of studies such as these are used to evaluate the efficacy of currently recommended preventive measures and to identify additional preventive measures to protect workers without adversely affecting patient care. For example, available data suggest that prevention of injuries in surgical and obstetrical settings will primarily involve changes in technique and personal protective equipment, such as development of thimbles or gloves which resist needle puncture while preserving tactile sensation. Changes in the design of surgical instruments may also be an effective strategy.

In contrast, further progress in the prevention of injuries related to drawing blood, starting an intravenous infusion, and other procedures commonly performed on hospital wards and in outpatient settings is likely to be accomplished primarily by changes in the design of needles and other medical devices. Data from studies of needlestick injuries by Dr. Janine Jagger and colleagues at the University of Virginia indicate substantial differences in the rates of injury associated with different

needle devices, with some devices being much safer than others. Dr. Jagger's data suggest that 88% of needlestick injuries could potentially be eliminated by product redesign or substitution. These results support data from the CDC surveillance project of workers exposed to HIV-infected blood. In this project, at least 45% of injuries were potentially preventable by device modification or substitution. These were injuries which occurred while recapping a used needle, using a needle to administer medication into an intravenous line or heparin lock, and due to improper disposal of a used needle.

Although numerous new or modified devices purporting to reduce the incidence of needlesticks are being advertised in the medical marketplace, few of these devices have been clinically evaluated for safety, efficacy in infection control, or effect on patient care. Qualitative evaluation safety check sheets for sharps, disposal containers and anti-needlestick devices, developed under cooperative agreement, have been distributed by the Service Employees International Union in their "Needlestick Factpack." CDC is currently providing financial and technical support for device evaluation activities through its National Center for Infectious Diseases, National Institute for Occupational Safety and Health, and National Center for Prevention Services. In the letter of invitation you asked about the budget for our medical device activities. In fiscal year 1991, CDC intramural and

extramural funding for device-related activities totalled approximately \$1.5 million.

CDC and other federal agencies have clearly signalled the need for the development and use of safer medical devices. The importance of engineering controls, including intrinsically safe devices and appropriate equipment modifications for preventing transmission of bloodborne pathogens in health-care settings has been recommended in: 1) A Joint Advisory Notice: Protection Against Occupational Exposure to Hepatitis B Virus and Human Immunodeficiency Virus sent to employers by the Departments of Labor and Health and Human Services in October 1987 (page 8), 2) CDC Guidelines for Prevention of Transmission of Human Immunodeficiency Virus and Hepatitis B Virus to Health-care and Public Safety Workers published in 1989 (MMWR 1989;38(no. S-6): page 10), 3) CDC Recommendations for Preventing Transmission of Human Immunodeficiency Virus and Hepatitis B Virus to patients During Exposure-Prone Invasive Procedures published in 1991 (MMWR 1991;40(No.RR-8):page 6), and 4) a CDC assessment entitled Human Immunodeficiency Virus Transmission in Health Care Settings: Risk and Risk Reduction, published in the American Journal of Medicine in 1991 (Am J Med 1991;91(suppl 3B): pages 294S and 297S). This assessment was published as part of the Proceedings of the Third Decennial International Conference on Nosocomial Infections co-sponsored by CDC; it was mailed to all

state health departments and to over 7,000 member hospitals of the American Hospital Association. With the subcommittee's approval, I would like to submit these documents for the record.

The FDA has regulatory authority over the entry of new medical devices into the market and will report on its activities today. Finally, the Occupational Safety and Health Administration (OSHA) recently promulgated a standard for occupational exposure to bloodborne pathogens. According to this standard, employers are required to implement an exposure reporting and control plan for their employees. In OSHA's assessment, methods for exposure prevention include engineering controls, a category which includes the use of safer medical devices.

To focus attention on the performance safety of medical devices, CDC, FDA, and OSHA are co-sponsoring a conference entitled Frontline Healthcare Workers: A National Conference on Prevention of Device-Mediated Bloodborne Infections in Washington, D.C., August 17-19, 1992. The purpose of this conference is to stimulate development, evaluation, and use of safer medical devices by facilitating the sharing of ideas and the establishment of closer working relationships among researchers, device manufacturers, purchasers, users, and appropriate government agencies.

In summary, CDC believes that prevention of bloodborne pathogen transmission in health-care settings depends primarily on prevention of percutaneous injuries. When feasible, use of engineering controls, including safer medical devices, is the preferred method of injury prevention. CDC is conducting a variety of activities to assist in the development and evaluation of such devices. These efforts will continue in the future, in cooperation with other federal agencies.

Thank you again for the opportunity to appear here today. Dr. Mullan and I would be happy to answer any questions you may have.

Health Care Workers With AIDS

National Surveillance Update

Mary E. Chamberland, MD, MPH; Lois J. Conley, MPH; Timothy J. Bush;
Carol A. Ciesielski, MD; Teresa A. Hammett, MPH; Harold W. Jaffe, MD

Objectives.—To characterize health care workers with the acquired immunodeficiency syndrome (AIDS) in the United States and to evaluate the role of occupational transmission of the human immunodeficiency virus (HIV).

Data Source.—National AIDS surveillance data.

Methods.—Health care workers with AIDS are reported to the Centers for Disease Control by state and local health departments. Health care workers who do not report a nonoccupational risk for HIV infection are termed *undetermined risk* cases and are investigated by health departments using a standard protocol.

Results.—Through June 30, 1990, there were 5425 cases of AIDS in health care workers reported in the United States. Three of these workers developed AIDS following well-documented occupational exposure to HIV-infected blood. Of the 539 health care workers initially reported without a nonoccupational risk, follow-up investigations were completed for 303. Nonoccupational risk factors were established for 237 (78.2%) of the 303 investigated health care workers; 66 workers (21.8%) remained in the undetermined category. Follow-up information was incomplete for 236 health care workers who also remained in the undetermined category, resulting in 5120 health care workers (94.4%) with AIDS with nonoccupational risks for HIV infection. Overall, health care workers were more likely than non-health care workers with AIDS to have an undetermined risk for HIV infection (5.6% vs 2.8%; $P < .001$). While many of the 66 investigated health care workers had jobs involving contact with patients and/or potential contact with blood, none reported percutaneous, mucous membrane, or cutaneous exposures to blood or body fluids known to be infected with HIV.

Conclusion.—Surveillance data suggest that most health care workers with AIDS acquired their HIV infection through a nonoccupational route.

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NATIONAL surveillance for the acquired immunodeficiency syndrome (AIDS) is one important source of de-

scriptive data regarding infection with the human immunodeficiency virus (HIV) in health care workers. The AIDS surveillance data, along with prospective studies evaluating the risk of HIV infection following exposure to the blood and/or body fluids of HIV-infected persons,¹⁻³ cross-sectional seroprevalence surveys (ADA News. 1988;19:4),^{4,6} and individual case reports, provide a composite picture of the status of occupationally acquired HIV infection. This ar-

ticle updates previously published national surveillance data on AIDS in health care workers in the United States.⁷

METHODS

Definitions

The AIDS surveillance case report form collects information on employment "since 1978 in a health care or clinical laboratory setting." For surveillance purposes, persons who indicate such employment are defined as *health care workers*. Standardized occupational codes are used to classify health care workers into occupational groups (eg, physician, nurse, and dentist).

Case Identification and Follow-up

Persons who meet the AIDS surveillance case definition are reported to the Centers for Disease Control (CDC) by state and local health departments. Follow-up investigations are conducted by health department personnel for all persons with an undetermined risk for HIV exposure using methods previously described.^{8,9} In addition to persons who currently are under investigation by local health department officials, the undetermined category includes persons whose exposure history is incomplete because of death, refusal to be interviewed, or unavailability for follow-up, and persons who were interviewed or for whom other follow-up information was available and no exposure mode was identified. Persons who have a risk factor identified at the time of follow-up are reclassified into the appropriate exposure category. Health care workers in the undetermined risk category (ie,

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Table 1.—Comparison of Health Care Workers With the Acquired Immunodeficiency Syndrome (AIDS) and Other Adults With AIDS, by Exposure Category, Through June 30, 1990*

Exposure Category	Health Care Workers With AIDS, No. (%)	Other Adults With AIDS, No. (%)
Men†		
Male homosexual-bisexual contact	3855 (79.3)	65 002 (66.5)‡
IV drug use	247 (5.1)	18 139 (18.8)‡
Male		
Male homosexual-bisexual contact and IV drug use	380 (7.8)	7296 (7.8)
Hemophilia-coagulation disorder	35 (0.7)	943 (1.0)
Heterosexual contact	78 (1.5)	2238 (2.3)§
Receipt of transfusion of blood, blood components, or tissue	56 (1.2)	1594 (1.6)§
Undetermined	216 (4.4)	2447 (2.5)‡
Total	4854 (100.0)	97 661 (100.0)
Women†		
IV drug use	139 (24.9)	5399 (53.4)‡
Hemophilia-coagulation disorder	3 (0.5)	22 (0.2)
Heterosexual contact	257 (46.1)	3189 (31.5)‡
Receipt of transfusion of blood, blood components, or tissue	73 (13.1)	941 (9.3)§
Undetermined	66 (11.4)	568 (5.6)‡
Total	558 (100.0)	10 119 (100.0)

*Excludes 24 177 persons for whom occupational information was missing or unknown and three health care workers who seroconverted to human immunodeficiency virus (HIV) and developed AIDS after documented exposures to HIV-infected blood. IV indicates intravenous.

† $P < .0001$, overall χ^2 analysis for health care workers with AIDS vs other adults with AIDS.

‡ $P < .0001$, χ^2 test by log linear models.

§ $P < .01$, χ^2 test by log linear models.

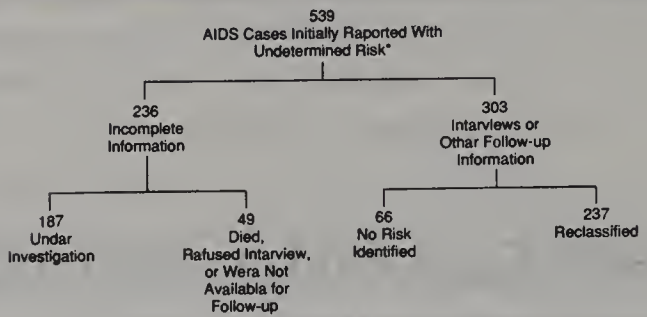
those who do not report nonoccupational risk factors) are given priority for investigation by health departments.

Data Analysis

This report includes AIDS surveillance data, as well as information derived from follow-up investigations of persons with an undetermined risk, reported to the CDC through June 30, 1990. Statistical testing included analysis by log linear models, χ^2 test for association, and Fisher's Exact Test. The acceptable type I error rate was 0.05. All P values are two-tailed.

RESULTS

As of June 30, 1990, there were 137 385 adults and adolescents older than 13 years with AIDS who had been reported to the CDC. Information regarding employment in a health care setting was available for 113 208 (82.4%) of these



Results of investigations of health care workers with the acquired immunodeficiency syndrome (AIDS) and an undetermined risk, reported through June 30, 1990. Asterisk indicates that an additional three workers seroconverted to the human immunodeficiency virus (HIV) and developed AIDS after documented exposures to HIV-infected blood. (The 237 workers were reclassified as follows: 137 male homosexual-bisexual contact; 24 intravenous drug use; four male homosexual-bisexual contact and intravenous drug use; 64 heterosexual contact; and eight received blood transfusions.)

persons, 5425 (4.8%) of whom were classified as *health care workers*.

The 5425 health care workers with AIDS were similar to other persons with AIDS in that most were men (89.7% and 90.6%, respectively), and the mean age in each group was 37 years. Among health care workers with AIDS, 61.9% were white, 27.2% were black, and 9.5% were Hispanic; among other persons with AIDS, 56.8% were white, 27.2% were black, and 15.1% were Hispanic ($P < .001$).

Of the 5425 health care workers with AIDS, three without other HIV risk factors seroconverted to HIV and developed AIDS after occupational exposures (two percutaneous and one non-intact skin) to HIV-infected blood.^{10,11} At the time of the initial report, 539 of the 5425 health care workers were initially classified in the undetermined risk category. However, subsequent investigations (details to follow) identified nonoccupational risk factors for 237, resulting in 5120 health care workers (94.4%) with AIDS who reported nonoccupational risks for HIV infection. Among those who reported nonoccupational risks, male health care workers with AIDS were significantly more likely than other men with AIDS to report homosexual contact, and both male and female health care workers were less likely to report intravenous drug use (Table 1). The proportion of health care workers with AIDS in the undetermined risk category (5.6%) differed significantly from the proportion of other adults with AIDS and an undetermined risk (2.8%) ($P < .001$). Female health care

workers were nearly 3.5 times more likely than male health care workers to have an undetermined risk reported (15.4% compared with 4.4%) and were nearly three times more likely than other women with AIDS to be classified in the undetermined category (15.4% compared with 5.6%).

Of the 539 health care workers who initially did not report a nonoccupational risk factor for HIV infection, follow-up information was available for 303 workers: 237 (78.2%) had risk factors established and were reclassified into the appropriate exposure category, and 66 (21.8%) did not have any nonoccupational or occupational risks conclusively documented after follow-up (Figure). In comparison, 82.9% of non-health care workers who initially reported no known risk factors for AIDS had risk factors identified on follow-up and were reclassified. In addition to these 66 investigated workers, the undetermined category included 187 persons for whom investigations were in progress and 49 persons who had either died or refused to be interviewed or who were not available for follow-up.

Previous experience suggests that risk factors for HIV infection ultimately will be identified for many health care workers classified in the undetermined category and for whom investigations are ongoing. Accordingly, the following analyses were restricted to the 66 workers who could not be reclassified into a risk group after investigations were completed to evaluate the possibility of occupationally acquired HIV infection. The 66 investigated health care workers were

Table 2.—Comparison of Occupations of Investigated Health Care Workers With an Undetermined Risk and Health Care Workers With an Identified Risk for HIV Infection*

Occupation	Risk Status of Health Care Workers With AIDS	
	Investigated and Undetermined Risk, No. (%)	Identified Risk, No. (%)†
Physician, nonsurgeon	13 (19.7)	570 (12.0)
Surgeon-obstetrician‡	1 (1.5)	33 (0.7)
Dentist or other dental worker	2 (3.0)	140 (2.9)
Nurse	6 (9.1)	1056 (22.2)
Aide, attendant, or orderly	14 (21.2)	841 (17.7)
Technician, including laboratory technician	8 (12.1)	757 (15.9)
Therapist, including respiratory therapist	1 (1.5)	272 (5.7)
Emergency medical technician‡	1 (1.5)	78 (1.8)
Embalmer or morgue worker	3 (4.5)	33 (0.7)§
Maintenance worker or housekeeper	10 (15.2)	251 (5.3)¶
Other	7 (10.8)	724 (15.2)
Total	66 (100.0)	4755 (100.0)

*HIV indicates human immunodeficiency virus; AIDS, acquired immunodeficiency syndrome.

†Occupation was not specified for 384 health care workers.

‡Information was incomplete for these occupations because specific codes were not instituted until September 1987.

§ $P = .013$, Fisher's Exact Test.

¶ $P = .003$, Fisher's Exact Test.

different from the nearly 7 million persons employed in hospitals and health services in the United States in that they were more likely to be men (69.7% vs 23.1%) and black (37.9% vs 14.1%) or Hispanic (12.1% vs 4.9%).¹²

When health care workers were questioned about past occupational exposures, 35 (61.4%) of 57 workers who responded reported needlesticks and/or mucous membrane or cutaneous exposures to blood or other body fluids; 32 (91.4%) reported a needlestick injury. However, none of these exposures were known to involve a patient or a clinical specimen with documented HIV infection at the time of exposure, and none of the workers were evaluated at the time of exposure to document HIV seroconversion.

When the proportional distribution of the 66 investigated health care workers was compared with that of health care workers who reported nonoccupational risk factors, a statistically larger proportion of maintenance workers and embalmers or morgue workers were categorized with an undetermined risk

(Table 2). One of the morticians only rarely, if at all, performed embalming procedures and, hence, would not have had the opportunity to come into contact with blood or body fluids. Five of 10 maintenance workers reported sustaining a needlestick and/or mucous membrane or nonintact skin exposure to blood or other body fluids in the previous 10 years.

COMMENT

Health care workers consistently have comprised 5.0% or less of AIDS cases reported to the CDC each year⁷ and, as such, are not overrepresented among persons with AIDS when compared with the proportion of the US labor force employed in health services (6.0%).¹² Most health care workers with AIDS have reported nonoccupational risk factors for HIV infection. Although the possibility of occupational transmission cannot be excluded entirely, each did have a history of other exposures known to increase the probability of HIV infection, and none implicated occupational transmission as a source for their HIV infection.

Three health care workers reported through AIDS surveillance developed AIDS following well-documented occupational exposure to HIV-infected blood. In addition to these three, the CDC is aware of at least 20 additional health care workers in the United States who have not developed AIDS but who are reported to have seroconverted to HIV after a documented percutaneous injury or mucous membrane or skin exposure to blood, and one laboratory worker who seroconverted following a mucocutaneous exposure to concentrated virus.¹³ In addition to the 66 investigated health care workers with AIDS and an undetermined source of infection, there are 16 health care workers with HIV infection (but not AIDS) who have not reported nonoccupational risk factors.¹³ Although these 16 workers reported that their HIV infection was occupationally acquired, neither the time of exposure nor the source of infection was documented. There are at least 11 published cases of occupationally acquired HIV infection reported from outside the United States.¹⁴

Intensive follow-up of health care workers with an undetermined risk for AIDS who are reported to state and local health departments is done to elucidate possible instances of occupational transmission. Since 1987, a higher proportion of health care workers compared with other persons with AIDS have been classified in the undetermined risk category. Whether or to what extent this excess represents an attributable risk

secondary to occupational transmission is not clear. Follow-up interview information suggests that some of these workers had opportunities for potential occupational exposure to HIV. However, the HIV serostatus of the patients to whom they were exposed was not known. While it is likely that some of the 66 investigated health care workers acquired their HIV infection through an occupational route, it is also likely that some had nonoccupational risk factors that they did not report or recognize (eg, sexual contact with a partner not suspected or known to be infected). This hypothesis is supported by the striking overrepresentation of men among this group of investigated health care workers with AIDS (69.7%) when compared with the proportion of health care workers in general who are men (23.4%). Similarly, men are overrepresented among persons with AIDS who became infected through sex with other men or by intravenous drug use.

It was also not possible to determine if the observed excess of embalmers or morgue workers and maintenance workers among the investigated health care workers with an undetermined risk for AIDS compared with health care workers with nonoccupational risks was attributable to occupational transmission of HIV. An appreciable level of hepatitis B infection among morticians and housekeeping personnel has been documented,^{15,16} and in one hospital-based study, housekeepers had the highest incidence rate of self-reported needlestick injuries.¹⁷ However, physicians, surgeons, and dentists—occupations also associated with an elevated risk for hepatitis B infection—were not overrepresented among investigated health care workers with an undetermined risk. Also, it is likely that the proportional distribution of specific occupations among health care workers with AIDS is different from that of health care workers in general, especially given the overrepresentation of men among health care workers with AIDS. These observations suggest that the excess of embalmers and maintenance workers with an undetermined risk for AIDS could be spurious.

The AIDS surveillance provides one approach to monitoring occupationally acquired HIV infection and, as such, have certain strengths. Surveillance has been established throughout the United States and incorporates systematic data collection and follow-up procedures. Mortality studies suggest that 70% to 90% of HIV-related deaths are reported as AIDS through national surveillance.¹⁸ However, occupationally acquired HIV infection is difficult to determine with

certainly unless there is a specific, well-documented occupational exposure, the source patient or clinical specimen is known to be HIV infected, and seroconversion to HIV is detected in the worker following exposure. The retrospective nature of follow-up of persons reported with AIDS through surveillance makes assessment of these factors often difficult, if not impossible. Additional limitations include reliance on self-reported medical, social, and occupational data, which often cannot be corroborated by independent sources, and lack of detailed data on the nature and frequency of occupational blood contact experienced by these individuals. The Public Health Service's recommendation for system-

atic evaluation, counseling, and follow-up in a timely fashion of workers who sustain an occupational exposure should assist in improvement of documentation procedures.¹⁹ Also, at this time, national surveillance data include only persons with AIDS and not those with the entire spectrum of HIV disease. The CDC and state and local health departments currently are expanding their surveillance efforts to implement standardized reporting and investigation of health care workers and others with HIV infection that may be the result of occupational exposure but that does not yet meet the AIDS case definition.²⁰

The increasing number of persons being treated for HIV-associated illnesses makes it likely that more health

care workers will encounter persons infected with HIV. Recommendations made by the CDC to use universal precautions when caring for all patients^{19,21,22} and the Occupational Safety and Health Administration's recently proposed standard,²³ which sets forth specific provisions, including engineering and work practice controls, personal protective clothing and equipment, and training and medical follow-up, can help to reduce this risk.

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Human Immunodeficiency Virus Transmission in Health Care Settings: Risk and Risk Reduction

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Surveillance data and case reports document that health care workers (HCWs) risk occupationally acquired human immunodeficiency virus (HIV) infection. Transmission of HIV to patients of an infected HCW during invasive procedures has also been reported. The risk to a susceptible HCW depends on the prevalence of HIV infection among patients, the nature and frequency of occupational blood exposures, and the risk of transmission per exposure. Blood exposure rates vary by occupation, by procedure, and by compliance with preventive measures. Future efforts to protect both HCWs and patients must include improved surveillance, risk assessment, study of postexposure prophylaxis, and an emphasis on exposure prevention, including development of safer medical devices, work practices, and personal protective equipment that are acceptable to HCWs and do not adversely affect patient care.

Information on human immunodeficiency virus (HIV) transmission in health care settings is derived from a variety of sources, including surveillance data, case reports, and risk-assessment studies.

SURVEILLANCE DATA

As of September 30, 1990, the Centers for Disease Control (CDC) had received reports of 149,498 cases of AIDS in adults in the United States. Of 122,159 patients for whom information is available, 5,815 (4.8%) reported a history of employment in a health care or clinical laboratory setting (Ciesielski C, personal communication). In comparison, about 5.7% of the United States labor force is employed in health services [1].

Of the 5,815 health care workers (HCWs) with the acquired immunodeficiency syndrome (AIDS), 94% fall within one or more well-recognized nonoccupational transmission categories, three people (<1%) seroconverted and subsequently developed AIDS after a documented occupational exposure to HIV-infected blood, and 6% have an undetermined risk. In contrast, 3% of the 116,344 non-HCWs with AIDS have an undetermined risk. The reasons for the difference may include an occupational risk of HIV infection in HCWs, an unwillingness of HCWs to report behavioral risks, or both. Of the 337 HCWs in the undetermined risk group, 60% are still under investigation to determine risk, 19% have either died, refused to be interviewed, or were lost to follow-up, and 20% (69 HCWs) could not be reclassified into a known transmission category after follow-up investigation.

Of these 69 workers, none had had a documented exposure to blood or other body fluids of a patient with AIDS or HIV infection, and approximately 40% did not recall having an exposure to blood or body fluids of any patient during the 10 years before their diagnosis of AIDS. Thus, the proportion of these workers who acquired infection due to occupational exposure cannot be determined.

As of June 30, 1991, CDC was aware of 40 HCWs in the United States reported to have occupationally acquired HIV infection or AIDS (Ciesielski C, personal communication). In 24 cases, seroconver-

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TABLE I
HIV Seroprevalence in Selected Groups of Health-Care Workers (HCWs)

Worker Group	Number Tested	Number Positive (%)	Number Positive with Community Risk	Prevalence Excluding Seropositives with Community Risk (%)	Reference
Orthopedic surgeons, U.S.A. and Canada (1991 annual meeting)	3,420	2 (0.06)	2	0.00	[3]
Physicians and dentists in U.S. Army Reserve	3,347	3 (0.09)	NA	NA	[4]
Dentists					
San Francisco	304*	0 (0)	0	0	[7]
Sacramento	89	0 (0)	0	0	[6]
USA, 1986 annual meeting and New York City	1,132*	1 (0.09)	0	0.09	[5]
USA, 1987 annual meeting	1,195	0 (0)	0	0	[8]
USA, 1988 annual meeting	1,165	1 (0.09)	0	0.09	[9]
USA, 1989 annual meeting	1,480	0 (0)	0	0	[9]
Denmark	961	0 (0)	0	0	[10]
Dental hygienists, New York and Sacramento	167	0 (0)	0	0	[5,6]
Dental assistants, New York and Sacramento	176	0 (0)	0	0	[5,6]
Hemodialysis staff, New York, Paris, Chicago, Brussels, Florence	356	0 (0)	0	0	[11-15]
HCW blood donors, USA, 20 urban regions	32,730†	48 (0.15)	31	0.05	[16]

NA = not available.

*Persons with community risk not included.

†Estimated number of blood donors who were HCWs.

sion was documented after percutaneous injury, mucous membrane, or skin exposure to blood (23 HCWs) or concentrated virus (1 laboratory worker). In addition, 16 HCWs with HIV infection (without AIDS) reported that their infection was occupationally acquired, although the time or source of infection is not documented. There are at least 11 published cases reported from outside the United States [2]. It is essential that suspected cases of occupational HIV infection be reported to appropriate health authorities so that the frequency and circumstances of these infections can be assessed and appropriate preventive measures developed.

RISK ASSESSMENT STUDIES

Limited risk assessment data are available from HIV seroprevalence surveys and from prospective studies of exposed HCWs. Ongoing studies may also permit crude risk estimates to be derived indirectly; i.e., from data on patient seroprevalence, the frequency of blood contact by workers, and the risk of infection per exposure.

Seroprevalence Data

Available HIV seroprevalence data from selected HCW groups [3-16] are summarized in Table I. A major limitation of these studies is that the extent of exposure to HIV of most workers tested is not known. Also, some of these rates may be underesti-

mates if workers who knew or suspected that they might be positive declined to be tested.

In the United States, patient HIV seroprevalence varies widely according to location, diagnosis, and other factors, but in some hospitals this prevalence is appreciable. In one study in 26 sentinel hospitals in 21 cities, the HIV seroprevalence in patients with diagnoses not associated with HIV infection ranged from 0.1 to 7.8% [17].

Risk of Infection after Exposure

Prospective studies indicate that the risk of HIV transmission to a HCW due to a single percutaneous (i.e., needlestick or cut with a sharp object) exposure to HIV-infected blood is approximately 0.3%; (upper limit of the 95% confidence interval, 0.6%) [18-20]. This rate is an average of many types of percutaneous exposure from source patients in many stages of disease. Although there are likely to be subgroups of these exposures for which the risk of transmission is higher than 0.3% and subgroups for which it is lower, there are currently insufficient epidemiologic data to identify such subgroups.

Transmission of HIV after a mucous membrane or skin exposure to HIV-infected blood has also been reported [21], although the risk of transmission after such exposures is unknown because no seroconversions have been detected in cohort stud-

TABLE II

Prospective Studies of Blood Contact (BC) Among Operating and Delivery Room Personnel

Location	Number of Procedures	Percentage of Procedures With ≥ 1 BC	Percentage of Procedures with ≥ 1 Sharp Injury	Reference
San Francisco	1,307*	6.4	1.3	25
Atlanta				
Surgery	206	30.1	4.9	26
Obstetrics	230	32.2	1.7	27
Albuquerque	684*	27.8	3.1	28
Milwaukee	234	50.4	15.4	29
Saudi Arabia	2,016	NA	5.6	30
New York and Chicago	1,382	46.6	6.9	31

NA = not available.

*Includes endoscopic procedures.

ies of HCWs after mucous membrane and skin contact with HIV-infected blood [18–20, 22]. In these studies, the upper limit of the 95% confidence interval for the risk of HIV transmission after mucous membrane and skin contact with HIV-infected blood is 0.3% and 0.04%, respectively. In the cohort studies, no HCWs seroconverted after exposure to fluids other than blood.

Because of reports of delayed seroconversion in some studies of homosexual men, several investigators have used the polymerase chain reaction (PCR) to examine specimens from HCWs after exposure to HIV-infected blood [18,20,23,24]. None of a total of 237 seronegative workers was positive by PCR, except for three cases in one study. In these three cases enzyme-linked immunosorbent assay (ELISA) and Western blot antibody studies, p24 antigen, and viral culture were negative. Subsequently, PCR testing on two of these workers was negative [20]. These data, combined with data on several hundred HCWs who have remained seronegative when tested 2 or more years after exposure [18–20], suggest that seroconversion beyond 6 months after an occupational exposure, if it occurs, is likely to be uncommon.

Epidemiology of Blood Contact

Prospective studies among certain groups of HCWs have begun to describe the epidemiology of

blood contact, to define risk factors for blood contact, and to suggest that many contacts may be preventable.

At least seven prospective studies have assessed the percentage of operations in which one or more members of the surgical team sustained any blood contact (defined as a percutaneous injury, mucous membrane, or skin contact), and the percent in which one or more team members sustained a percutaneous injury [25–31] (Table II). These rates do not apply to an individual worker, since several workers are normally involved in one operation. The range of results might be attributable to differences in study methods, procedures observed, and the use of precautions by the surgical team.

In areas of the United States with a high AIDS incidence, CDC has conducted prospective studies in which HCWs in surgical, obstetric, and hospital emergency departments were observed while performing procedures to ascertain the frequency, and preventability of blood contact. In Table III, one HCW procedure is defined as one procedure done by one HCW. For example, one surgeon performing two operations equals two surgeon procedures. Also, two surgeons participating in a single operation equals two surgeon procedures. Blood contact rates appeared to be higher for obstetricians, for surgeons, and for emergency department workers who did not wear gloves while performing procedures.

In Table IV, the estimated number of procedures done per year by a member of each occupational group in these studies and data on the frequency of blood contact per HCW procedure have been used to estimate the frequency of blood contact per year for an individual HCW in the locations studied. Other investigators have collected prospective data on blood exposure frequency among physicians on medical wards [33] and retrospective data on injury frequency in dentists [5] (Table IV). All of these figures should be viewed as order of magnitude estimates. They may not be applicable to every worker in each occupational group and not all exposures may be comparable.

TABLE III

Blood Contact Rates Observed in Health Care Workers (HCWs), Preliminary Results of CDC Studies

Occupation	Number HCW Procedures Observed	Blood Contact Rate per 100 HCW Procedures	Sharp Injury Rate per 100 HCW Procedures	Reference
Surgeon (5 specialties)*	3,510	27.0	2.5	31
Scrub person (5 specialties)*	2,080	2.3	0.2	31
Obstetrician *	353	15.3	0.8	27
Hospital emergency department worker				
Gloved	8,098	1.6		
Not gloved	1,690	13.4	0.07	32

*General, orthopedic, gynecologic, cardiac, and trauma surgery.

Additional prospectively collected data on the epidemiology of blood contacts are needed. Interpretation of the data is facilitated if sharps exposures are clearly separated from other blood contacts and frequency data are expressed per individual worker per procedure and per unit of time.

When combined with information on patient seroprevalence, data such as these may be used to estimate the cumulative risk of HIV infection in groups of workers. Such calculations are most likely to be accurate at institutions in which patient seroprevalence and blood contact epidemiology are well defined [25].

EXPOSURE PREVENTION

Exposure prevention requires a combination of engineering controls that do not depend on worker compliance (e.g., self-sheathing needles), safe work practices and techniques, personal protective equipment (e.g., gloves), and training. Engineering controls, when feasible, are the preferred method of injury prevention; development and evaluation of safer medical devices and instruments are greatly needed [34].

Skin and mucous membrane contacts can frequently be prevented with barrier precautions and possibly changes in technique. Efficacy of barrier precautions in preventing blood contact was assessed in a CDC study conducted in six hospital emergency departments [32]. In this study, preliminary results indicate that blood contact rates ranged from 61% during thoracotomy to 2% during suturing. The frequency of glove use for commonly performed procedures ranged from 41% to 99%; glove use was more frequent in inner city than in suburban emergency departments. Blood contact rates were considerably lower for emergency department workers who wore gloves (Table V). These data strongly support the use of gloves to prevent blood contact by workers performing these procedures in hospital emergency departments. Prospective studies have also indicated that implementation of universal precautions reduced the number of blood exposures among physicians on medical wards [28] and other hospital workers [22].

In the studies in surgical and obstetric settings cited before, most skin and mucous membrane contacts could also have been prevented with additional barriers. However, the greatest risk of HIV transmission comes from percutaneous injuries, which are not usually preventable by currently available barriers. It is essential to learn more about the circumstances of these injuries and the devices with which they are associated.

In a CDC study in four hospitals, 99 sharp injuries were observed during 1,382 operations [31]. Preliminary results indicate that in 34 (34%)

TABLE IV
Estimates of Blood Contact Frequency in HCWs

Occupation	Number Procedures per Year	Number Blood Contacts per Year	Number Sharps Injuries per Year	Reference
Surgeon (5 specialties)*	500	135.0	12.5	31
Scrub person (5 specialties)*	500	11.5	1.0	31
Obstetrician	500	76.5	4.0	27
Hospital emergency department worker	625	24.2	0.4	32
Physician on medical ward	NA	31.2	1.8	33
Dentist	NA	NA	12.0	5

NA = not available.

*General, orthopedic, gynecologic, cardiac, and trauma surgery.

TABLE V
Efficacy of Gloves in Preventing Blood Contact (BC) with Skin, CDC Study in Hospital Emergency Department Workers: Preliminary Results [30]

Procedure	BC Rate per 100 Procedures		Relative Risk of BC for Ungloved vs. Gloved (95% CI)
	Ungloved	Gloved	
Obtaining arterial blood gas specimen	10.1	0.5	19.8 (4.6-85.3)
Starting intravenous line	16.3	1.2	13.0 (8.5-19.9)
Phlebotomy	5.7	1.0	5.4 (3.1-9.4)
Equipment disposal	22.3	1.2	19.1 (9.3-39.0)
Wound care	15.9	2.4	6.6 (4.2-10.6)

CI = confidence interval.

injuries, the surgeon was holding the tissue being sutured with his or her fingers. In seven (7%), the surgeon retrieved the suture needle with his or her fingers while suturing. Five injuries (5%) occurred while the suture needle was being adjusted in the needle holder. Seven injuries (7%) were related to unanticipated movements of coworkers, such as unannounced instrument passes. These data suggest that some injuries during surgery might be preventable by changes in technique. Additional measures may include development of puncture-resistant gloves and changes in instrument design. All such changes must be carefully evaluated to document that they enhance worker safety without compromising patient care.

AEROSOLS

Aerosols should not be confused with droplets and splashes. CDC recommends barrier precautions (such as face shields, masks, gowns) to prevent contact with droplets and splashes [35,36]. Aerosols are tiny, invisible particles that, unlike droplets, remain suspended in air for extended periods of time. While inspired particles 10-100 μ m in diameter may be deposited in the upper airway or in bronchi, true respirable aerosols capa-

ble of reaching alveoli consist of particles less than 10 μm in diameter. Aerosols require considerable mechanical energy (e.g., power equipment) to generate and are not likely to be present in most clinical settings. There are no known instances of transmission of a blood-borne pathogen by aerosol in a clinical setting. In studies conducted in dental operatories and hemodialysis centers, hepatitis B surface antigen could not be detected in the air during the treatment of hepatitis B carriers, including during procedures known to generate aerosols [37]. This suggests that detection of HIV in aerosols in clinical settings would also be uncommon, since the concentration of HIV in blood is generally lower than that of hepatitis B virus. Detection of HIV in a laboratory aerosol would not necessarily mean that HIV-containing aerosols are produced in clinical settings or that HIV is readily transmissible by aerosol in a clinical setting [38]. In the health care setting the major risks to HCWs are blood contact due to percutaneous injuries and, to a lesser extent, mucous membrane and skin contact. CDC is sponsoring research to assess the potential for aerosolization of blood and tissue during a variety of surgical procedures and to assess possible resulting hazards to surgical personnel. At this time, however, the possibility that HIV may be transmitted via aerosolized blood remains theoretical.

HUMAN IMMUNODEFICIENCY VIRUS TRANSMISSION TO PATIENTS DURING INVASIVE PROCEDURES

A recent report strongly suggested that HIV was transmitted to five patients during invasive procedures performed by a dentist with AIDS [39-41]. Three studies have been reported in which HIV testing was offered to patients of surgeons with AIDS [42-44].

In the largest and most systematic study, testing was offered to all patients who had been operated on by a general surgeon within 7 years prior to his diagnosis of AIDS [42]. Of 1,340 patients contacted, 616 (46%) were tested. One patient was HIV positive, a known intravenous drug user who may already have been infected at the time of surgery. Excluding this patient, the observed transmission rate was 0/615 patients tested (upper limit of the 95% confidence interval, 0.5%). Although these data are reassuring, the confidence interval does not exclude the possibility that transmission could occur at a low rate. Also, less than half of the patients contacted were tested and, since the date of the surgeon's HIV infection is unknown, it is unknown what proportion of the patients tested were operated on while he was infective.

In two other studies, 75 and 62 patients of surgeons with AIDS were tested [43,44]. All patients were HIV seronegative, although in one study [39], most patients were tested less than 90 days after surgery. Thus, if any patients became infected during surgery, they may not yet have developed HIV antibodies when tested. In a fourth study, none of 143 patients of a dental student with HIV infection tested positive for HIV [45].

To estimate patient risk precisely, large numbers of patients must be evaluated. Procedures must be stratified by degree of invasiveness and other factors that might influence the risk of HIV transmission, such as whether the HCW had AIDS or a less severe form of HIV infection. In view of the difficulties in conducting and interpreting these studies, it seems unlikely that precise estimates of patient risk will be available soon. Using modeling techniques, the average risk of *sporadic* HIV transmission from an HIV-infected surgeon to a patient during an invasive procedure has been estimated by CDC as 2.4-24 per million [46, 47] and by Rhame as 1-10 per million [48]. Lowenfels and Wormser have estimated this risk as 0.5-38.5 per million per hour of surgery [49]. In comparison, the risk of anesthesia-associated mortality is approximately 100 per million [50] and the risk of HIV infection from a transfusion of blood in the United States that has been screened as negative for HIV antibody is approximately 6.7-25 per million [51,52]. However, the models used to derive these patient risk estimates are not applicable during *outbreaks*, that is, unpredictable clusters of patients infected by a single HCW, in which the risk is much higher. More information is needed about the circumstances associated with outbreaks, in order to better estimate risk and to implement preventive measures. Using available data and input from expert consultants and members of the public, CDC has recently developed recommendations for preventing transmission of HIV and hepatitis B virus to patients during exposure-prone invasive procedures [53].

In conclusion, much has been learned about the risk and prevention of HIV transmission in health care settings, but additional data are needed. Future directions include more systematic surveillance of occupationally acquired HIV infection; additional HIV seroprevalence and incidence studies among workers with frequent blood exposures; better definition of the epidemiology of blood contact and the efficacy of preventive measures; development and evaluation of new devices and protective barriers; evaluation of postexposure prophylaxis; and assessment of the risk to patients who have undergone invasive procedures by HIV-

infected HCWs. Some of these topics are discussed in more detail by others in this symposium [54–56]. A sustained commitment will ensure maximum protection for HCWs and patients and the availability of optimal medical care for all who need it.

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

STATEMENT

BY

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

BEFORE THE

SUBCOMMITTEE ON REGULATION, BUSINESS OPPORTUNITIES, AND ENERGY

COMMITTEE ON SMALL BUSINESS

HOUSE OF REPRESENTATIVES

FEBRUARY 7, 1992

FOR RELEASE ONLY UPON DELIVERY

Mr. Chairman and Members of the Subcommittee:

Good morning. I am Thomas Arrowsmith-Lowe, AIDS Coordinator and the Deputy Director of the Office of Health Affairs in the Center for Devices and Radiological Health. With me is David West, Ph.D., Deputy Director of the Office of Device Evaluation in the Center. We are here today to discuss FDA's activities with regard to needlestick injuries.

Health care workers may face a risk of infection with a bloodborne pathogen as a result of exposures which occur in the health care setting. Percutaneous exposures, where the skin is penetrated by a sharp object, such as a needle, contaminated with the blood of another person, pose the greatest risk of bloodborne infection. Bloodborne infections transmitted in the health care setting include Hepatitis B Virus, Hepatitis C Virus, Human Immunodeficiency Virus (HIV), and others.

As a part of the Public Health Service effort to combat the AIDS epidemic, FDA has focused regulatory efforts on the role of medical devices which can reduce the risk of HIV transmission, such as condoms and gloves, and on medical devices which serve as a vehicle for transmitting the infection, such as syringes and needles. Syringes and needles used for injecting illegal drugs have been potentially responsible for 45,000 reported cases of AIDS. There have been three cases of AIDS in health care workers with documented

occupational exposures. In addition to these three cases, CDC will report today on additional cases of health care workers with documented seroconversions after occupational exposure to HIV-infected blood.

FDA is very concerned about the role of syringes in infecting both the small number of individuals infected occupationally and the tens of thousands of individuals infected through IV drug use. This strong concern about the need for products which would reduce the risks of bloodborne infections faced by health care workers prompted FDA to enter discussions with the Centers for Disease Control (CDC) about establishing dialogue between the clinical users of devices and those who manufacture these devices.

As you know, the Food and Drug Administration, through our Center, is responsible for ensuring the safety and effectiveness of medical devices, as provided by the Federal Food, Drug and Cosmetic Act. FDA has cleared for market both products which reduce the risk of injuries from syringes and products which prevent syringes from being reused for injecting drugs. These market clearances were accomplished under the Premarket Notification, or 510(k), process, where FDA must determine that the product is substantially equivalent to a previously marketed device. FDA looks at descriptive data for the new device, as well as performance data in many cases, and

compares those data to the previously marketed device. Approximately 5,000 new products are cleared annually for marketing through the 510(k) process. In FY 91, 21 needles and syringes were cleared for marketing. To date, over 50 anti-needlestick devices have been cleared for marketing through the 510(k) process.

Additionally, FDA has established a policy for the expedited review of Investigational Device Exemption (IDE) and Premarket Approval Applications (PMAs). This policy is for devices intended for use in diagnosis, therapy, or prevention of life-threatening or severely debilitating illnesses where no satisfactory alternative product is available. Such a process could be applied to 510(k)s where no alternative product is currently available.

We also have in the Center a Division of Small Manufacturers Assistance (DSMA), which received over 7,500 inquiries regarding the marketing of AIDS-related medical devices, including barrier devices, as well as needlestick prevention devices. Most of the anti-needlestick devices were developed by small companies, many of which are not fully aware of the FDA regulations in this area. DSMA will be heavily involved in the training sessions that will be incorporated into the August conference discussed below.

In April 1991, FDA received a Citizen's Petition from the Service Employees International Union. The petition requests that FDA undertake several regulatory and administrative actions, including sponsorship of a public conference on needlestick injuries and methods for reducing them through changes in medical devices. FDA will solicit public comments on this petition through publication of a notice in the Federal Register sometime next week. In that notice, we will note that FDA is co-sponsoring a meeting in August to address the needlestick issue. Furthermore, in the Federal Register response to the petition, FDA will also ask for comments on the approach of establishing a performance standard for needle-bearing devices.

This conference, co-sponsored with CDC and the Occupational Safety and Health Administration (OSHA), is designed to establish dialogue about device-mediated bloodborne infections between medical device users, manufacturers of devices, regulators of devices and workplace safety, and those who study the disease transmission. FDA, CDC, and OSHA are promoting the conference in the Morbidity and Mortality Weekly Report, through a mailing to health professional organizations and device manufacturers, through information published in health professional journals, and by a mailing to other interested parties.

That concludes my testimony, Mr. Chairman. We will be glad to respond to any questions you may have.

STATEMENT OF
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OCCUPATIONAL SAFETY AND HEALTH ADMINISTRATION
U.S. DEPARTMENT OF LABOR
BEFORE THE SUBCOMMITTEE ON REGULATION,
BUSINESS OPPORTUNITY AND ENERGY
COMMITTEE ON SMALL BUSINESS
U.S. HOUSE OF REPRESENTATIVES

FEBRUARY 7, 1992

Mr. Chairman and Members of the Subcommittee:

Thank you for the opportunity to discuss the Occupational Safety and Health Administration's (OSHA) efforts to protect workers from occupational exposure to bloodborne diseases. OSHA is particularly proud of its leadership in promulgating the standard on bloodborne pathogens for several reasons. The Congress directed OSHA to issue the standard by December 1, 1991, and we met the deadline. The standard represents the agency's response to one of the emerging health issues of the 1990s. By promulgating the bloodborne pathogens standard OSHA has shown that it can successfully adapt its regulatory structure to new and emerging hazards such as Human Immunodeficiency Virus (HIV).

History of the Standard

OSHA began to address the problem of bloodborne diseases as early as 1983 when the agency issued a set of voluntary guidelines designed to reduce the risk of occupational exposure

to the Hepatitis B Virus (HBV). The guidelines, which were sent to employers in the healthcare industry, included a description of the disease, recommended work practices to protect employees, and recommendations for the use of the Hepatitis B vaccine.

OSHA received petitions requesting a standard for bloodborne diseases in September 1986. On October 30, 1987, the Department of Labor and the Department of Health and Human Services published a Joint Advisory Notice entitled, "Protection Against Occupational Exposure to Hepatitis B Virus and Human Immunodeficiency Virus." The Notice, along with a pamphlet written by OSHA for healthcare workers, was mailed to more than 600,000 employers, employee representatives, and trade and professional associations.

OSHA initiated rulemaking for the bloodborne standard with an Advance Notice of Proposed Rulemaking in November 1987 and issued the final standard in December 1991. In developing the final rule, OSHA reviewed more than 3,000 written comments and received testimony from more than 400 participants in public hearings which were held in Washington, D.C., Chicago, New York, Miami, and San Francisco.

Provisions

The standard applies to any employer with employees who may reasonably be anticipated to come into contact with human blood or other potentially infectious materials while performing duties

at work. It covers almost 5 million workers, most of whom are employed in healthcare facilities such as hospitals, nursing homes and the offices of physicians and dentists. Other workplaces where exposures may occur include mortuaries, emergency response situations, correctional facilities and laundries that service the health care industry. OSHA estimates that the regulation will prevent approximately 200 deaths and approximately 9000 Hepatitis B infections each year.

Most providers of health care and related services require employees to confront an array of potentially hazardous situations. OSHA chose not to mandate specific engineering requirements for eliminating hazards. A specific device might quickly become outdated in workplaces with dynamic environments, such as hospitals, where there are often new treatments and rapid advances in medical science. Therefore, OSHA's bloodborne standard is performance-oriented, allowing employers to craft the most protective and cost-effective programs possible.

The standard is based on the adoption of the Centers for Disease Control's universal precautions as a method of infection control. This approach assumes that all human blood, certain body fluids, and other potentially infectious materials can be sources of infectious disease. To minimize employees' risk of contracting bloodborne diseases, employers are required to use a combination of engineering controls, work practices, personal protective equipment, training, the Hepatitis B vaccine, and medical follow-up after an exposure incident. Employers must

develop hazard abatement measures which best suit the workplace and accomplish the objective of protecting workers from contact with blood or other potentially infectious materials.

Employers must first develop an exposure control program that identifies employees who have occupational exposure to blood or other potentially infectious materials. The control program is to set forth a schedule for implementing measures to reduce risk. Employers are also required to develop procedures to evaluate the circumstances surrounding exposure incidents such as needlesticks. By evaluating each exposure incident, the employer can take steps to prevent further exposures from occurring. Appropriate medical follow-up and counseling must be made available to employees who have an exposure incident.

The standard requires that each employer offer the Hepatitis B vaccine, at no cost, to all employees who are exposed through their work to blood and other potentially infectious materials. Employees who choose not to accept the vaccine must sign a declination form. If they change their minds later, they may still receive the vaccine.

Employers must institute engineering and work practice controls as the primary means of eliminating occupational exposure to bloodborne pathogens. In general, engineering controls, such as self-sheathing needles or biosafety cabinets, isolate or remove the hazard. When occupational exposure in a workplace remains after institution of engineering controls and work practices, employers must provide personal protective

equipment as supplemental protection. They must ensure also that it is used properly. Protective equipment includes gloves, coats, gowns, masks, eye protection and face shields. These items serve as a barrier between the infectious material and the worker.

Needlesticks are a serious danger to healthcare workers. The risk of contracting a Hepatitis B infection following exposure with a needle contaminated with blood from an individual infected by HBV is between 60 and 300 per 1000. The risk of contracting HIV is between 3 and 4 per 1000. Handling and discarding of needles warrants special attention. To address this hazard, the bloodborne pathogens standard contains specific provisions dealing with contaminated needles. It requires that contaminated needles and other contaminated sharp instruments not be removed or recapped unless the employer can demonstrate that no alternative is feasible or that such action is required for a specific medical procedure. If recapping is necessary, it must be done by a mechanical device or by a one-handed method. Shearing or breaking of contaminated needles is prohibited. Immediately, or as soon as possible after use, contaminated reusable sharps must be placed in containers that are puncture-resistant, leakproof, and labeled or color-coded.

Proper housekeeping measures are required by the bloodborne standard. All equipment and working surfaces must be cleaned and decontaminated after contact with blood or other potentially infectious material. Regulated waste must be placed in

containers which are closable, constructed to prevent leakage, and properly labeled. Contaminated laundry must be placed in bags at the location of use and must be handled as little as possible.

Information and training are essential components of the standard. To ensure that employees receive adequate warning about the hazards of bloodborne pathogens, employers are required to provide information through biohazard labels, signs and training. Employers must also ensure that all employees participate in a training program when they are first assigned to a task involving exposure to blood or other potentially infectious materials and at least annually thereafter. The training program must deal with all aspects of the standard and must include an opportunity for questions and answers. All trainers must be knowledgeable about the standard. The value of training and education is demonstrated by a hospital which provided information to OSHA during the public hearings on the proposed standard. The facility reported that use of personal protective equipment by its employees increased from approximately 50-75% to 95-98% when proper work practices were explained and enforced.

Employers are responsible for maintaining medical records for each employee, and these records must be kept confidential. The medical records must be kept for the duration of employment plus 30 years. Employers must keep records of the training received by employees for three years.

Enforcement

The bloodborne pathogens standard will become effective on March 6, 1992. By May 5, employers must complete their exposure control plans. Initial training must be given by June 4, and all other provisions will be in effect by July 7, 1992.

Twenty-three States and two territories operate their own occupational safety and health plans, which are evaluated by OSHA to ensure effectiveness. The States must adopt a comparable standard by June 6, which is six months after publication of the Federal rule. Public employees are not covered in those States which do not operate State-OSHA programs. However, we have written to the Governors of these jurisdictions encouraging them to extend the protection of the standard to public employees exposed to bloodborne diseases.

OSHA already has considerable enforcement experience in the healthcare industry. Since 1987, OSHA has enforced the "General Duty Clause" of the Occupational Safety and Health Act, as well as certain general industry standards, in the health care sector. The "General Duty Clause" requires that employers furnish employees workplaces free from recognized hazards likely to cause death or serious physical harm. Among the standards which OSHA has enforced in healthcare facilities are rules for: (1) use of personal protective equipment, including gloves, gowns, and eyewear; (2) housekeeping; (3) tagging; and (4) waste disposal. In the past two years, OSHA conducted 767 inspections for

bloodborne hazards and found more than 3500 violations.

We are preparing OSHA's Compliance Safety and Health Officers to enforce the new standard. A compliance directive, describing the proper way to conduct healthcare inspections, is in preparation. OSHA's Training Institute, which instructs Federal and State compliance officers, provides a course on Biohazards which includes instruction on the bloodborne standard. The course is given at the Institute in Des Plaines, Illinois and at locations in Michigan and California. There is also a course of Laboratory Safety and Health, which includes some instruction on biological hazards. In addition, the Training Institute is conducting "Train-the Trainer" sessions on the bloodborne standard and its enforcement directive this month. The instruction is designed to allow Federal and State personnel to provide instruction to others. Approximately 150 compliance officers will participate in the sessions.

Outreach Efforts

The bloodborne standard will be effective in protecting workers only if employers and employees are aware of its provisions and knowledgeable about how to comply. To provide assistance, OSHA has initiated an outreach program on the standard. The program includes:

-Videotape. A videotape explaining the standard will

be available at all OSHA Regional and Area Offices, which are located throughout the Nation, as well as at State OSHA offices. The videotape is also being distributed to the State consultation offices which give advice about OSHA, upon request, to employers.

-Information Packets. By mid-February, each Regional Office will have available for the public copies of an informational package that describes the standard, the Hepatitis B vaccination program and other information about bloodborne pathogens. 20,000 copies of this package will be sent to OSHA's offices.

-Fact Sheets. Each Fact Sheet will highlight an individual requirement of the standard, such as proper use of sharps, personal protective equipment, and other provisions. A total of six Fact Sheets will be issued in the next several months. They will be available upon request.

-Booklets. OSHA will issue a booklet outlining general provisions of the standard in both English and Spanish. There also will be four more specialized booklets targeted to dental offices, emergency responders, as well as long-term and acute care facilities.

-Conference. On August 17-19, 1992, the Centers for Disease Control, the Food and Drug Administration, and OSHA will cosponsor a National Conference on Prevention of Device-Mediated Bloodborne Infections. The conference will focus attention on injuries from sharps and the safety of medical devices and instruments in all healthcare settings. We estimate there will be between 500-700 participants.

In addition to information efforts associated with the standard, OSHA has awarded almost \$300,000 to three non-profit organizations for the purpose of improving employee awareness and knowledge about the hazards of bloodborne disease in the workplace. The United Food and Commercial Workers International Union is using the funds to educate workers in small health care facilities. The National Foundation of Funeral Services is training 2000 funeral home workers on the hazards of bloodborne pathogens. The Butterworth Health Corporation is developing materials and training workers in health care facilities on the hazards of bloodborne pathogens and ways to prevent infections.

Mr. Chairman, this concludes my prepared statement. We

believe that the Department and OSHA's leadership in issuing the standard on bloodborne pathogens will have a far-reaching impact in protecting workers, not only because of its particular provisions, but because it may serve as a prototype for our approach to solving other health hazards which emerge in the years to come. I will be pleased to answer any questions.

Department of Labor / Department of Health and Human Services

JOINT ADVISORY NOTICE

**Protection Against Occupational Exposure To
Hepatitis B Virus (HBV) And
Human Immunodeficiency Virus (HIV)**

October 19, 1987

Department of Labor / Department of Health and Human Services

JOINT ADVISORY NOTICE

Protection Against Occupational Exposure To Hepatitis B Virus (HBV) And Human Immunodeficiency Virus (HIV)

I. Background:

Hepatitis B (previously called serum hepatitis) is the major infectious occupational health hazard in the health-care industry, and a model for the transmission of blood-borne pathogens. In 1985 the Centers for Disease Control (CDC) estimated [1] that there were over 200,000 cases of hepatitis B virus (HBV) infection in the U.S. each year, leading to 10,000 hospitalizations, 250 deaths due to fulminant hepatitis, 4,000 deaths due to hepatitis-related cirrhosis, and 800 deaths due to hepatitis-related primary liver cancer. More recently [2] the CDC estimated the total number of HBV infections to be 300,000 per year with corresponding increases in numbers of hepatitis-related hospitalizations and deaths. The incidence of reported clinical hepatitis B has been increasing in the United States, from 6.9/100,000 in 1978 to 9.2/100,000 in 1981 and 11.5/100,000 in 1985 [2]. The Hepatitis Branch, CDC, has estimated [unpublished] that 500-600 health-care workers whose job entails exposure to blood are hospitalized annually, with over 200 deaths (12-15 due to fulminant hepatitis, 170-200 from cirrhosis, and 40-50 from liver cancer). Studies indicate that 10% to 40% of health-care or dental workers may show serologic evidence of past or present HBV infection [3]. Health-care costs for hepatitis B and non-A, non-B hepatitis in health-care workers were estimated to be \$10 - \$12 million annually [4]. A safe, immunogenic, and effective vaccine to prevent hepatitis B has been available since 1982 and is recommended by the CDC for health-care workers exposed to blood and body fluids [1,2,5-7]. According to unpublished CDC estimates, approximately 30-40% of health-care workers in high-risk settings have been vaccinated to date.

According to the most recent data available from the CDC [8], acquired immunodeficiency syndrome (AIDS) was the 13th leading cause of years of potential life lost (82,882 years) in 1984, increasing to 11th place in 1985 (152,595 years). As of August 10, 1987, a cumulative total of 40,051 AIDS cases (of which 558 were pediatric) had been reported to the CDC, with 23,165 (57.8%) of these known to have died [9]. Although occupational HIV infection has been documented [10], no AIDS case or AIDS-related death is believed to be occupationally related. Spending within the Public Health Service related to AIDS has also accelerated rapidly, from \$5.6 million in 1982 to \$494 million in 1987, with \$791 million requested for 1988. Estimates of average lifetime costs for the care of an AIDS patient have varied considerably, but recent evidence suggests the amount is probably in the range of \$50,000 to \$75,000.

Infection with either HBV [1,2] or human immunodeficiency virus (HIV, previously called human T-lymphotrophic virus type III/lymphadenopathy-associated virus (HTLV III/LAV) or AIDS-associated retrovirus (ARV)) [11,12]

can lead to a number of life-threatening conditions, including cancer. Therefore, exposure to HBV and HIV should be reduced to the maximum extent feasible by engineering controls, work practices, and protective equipment. (Engineering controls are those methods that prevent or limit the potential for exposure at or as near as possible to the point of origin, for example by eliminating a hazard by substitution or by isolating the hazard from the work environment.)

II. Modes Of Transmission:

In the U.S., the major mode of HBV transmission is sexual, both homosexual and heterosexual. Also important is parenteral (entry into the body by a route other than the gastrointestinal tract) transmission by shared needles among intravenous drug abusers and to a lesser extent in needlestick injuries or other exposures of health-care workers to blood. HBV is not transmitted by casual contact, fecal-oral or airborne routes, or by contaminated food or drinking water [1,2,13]. Workers are at risk of HBV infection to the extent they are exposed to blood and other body fluids; employment without that exposure, even in a hospital, carries no greater risk than that for the general population [1]. Thus, the high incidence of HBV infection in some clinical settings is particularly unfortunate because the modes of transmission are well known and readily interrupted by attention to work practices and protective equipment, and because transmission can be prevented by vaccination of those without serologic evidence of previous infection.

Identified risk factors for HIV transmission are essentially identical to those for HBV. Homosexual/bisexual males and male intravenous drug abusers account for 85.4% of all AIDS cases, female intravenous drug abusers for 3.4%, and heterosexual contact for 3.8% [9]. Blood transfusion and treatment of hemophilia/coagulation disorders account for 3.0% of cases, and 1.4% are pediatric cases. In only 3.0% of all AIDS cases has a risk factor not been identified [9]. Like HBV, there is no evidence that HIV is transmitted by casual contact, fecal-oral or airborne routes, or by contaminated food or drinking water [12-14], and barriers to HBV are effective against HIV. Workers are at risk of HIV infection to the extent they are directly exposed to blood and body fluids. Even in groups that presumably have high potential exposure to HIV-contaminated fluids and tissues, e.g., health-care workers specializing in treatment of AIDS patients and the parents, spouse, children, or other persons living with AIDS patients, transmission is recognized as occurring only between sexual partners or as a consequence of mucous membrane or parenteral (including open wound) exposure to blood or other body fluids [10,11,13-16].

Despite the similarities in the modes of transmission, the risk of HBV infection in health-care settings far exceeds that for HIV infection [13,14]. For example, it has been estimated [14,17,18] that the risk of acquiring HBV infection following puncture with a needle contaminated by an HBV carrier ranges from 6% to 30% – far in excess of the risk of HIV infection under similar circumstances, which the CDC and others estimated to be a less than 1% [10,13,16].

Health-care workers with documented percutaneous or mucous-membrane exposures to blood or body fluids of HIV-infected patients have

been prospectively evaluated to determine the risk of infection after such exposures. As of June 30, 1987, 883 health-care workers have been tested for antibody to HIV in an ongoing surveillance project conducted by CDC [19]. Of these, 708 (80%) had percutaneous exposures to blood, and 175 (20%) had a mucous membrane or an open wound contaminated by blood or body fluid. Of 396 health-care workers, each of whom had only a convalescent-phase serum sample obtained and tested 90 days or more post-exposure, one—for whom heterosexual transmission could not be ruled out—was seropositive for HIV antibody. For 425 additional health-care workers, both acute- and convalescent-phase serum samples were obtained and tested; none of 74 health-care workers with nonpercutaneous exposures seroconverted, and three (0.9%) of 351 with percutaneous exposures seroconverted. None of these three health-care workers had other documented risk factors for infection.

Two other prospective studies to assess the risk of nosocomial acquisition of HIV infection for health-care workers are ongoing in the United States. As of April 30, 1987, 332 health-care workers with a total to 453 needlestick or mucous-membrane exposures to the blood or other body fluids of HIV-infected patients were tested for HIV antibody at the National Institutes of Health [20]. These exposed workers included 103 with needlestick injuries and 229 with mucous-membrane exposures; none had seroconverted. A similar study at the University of California of 129 health-care workers with documented needlestick injuries or mucous-membrane exposures to blood or other body fluids from patients with HIV infection has not identified any seroconversions [21]. Results of a prospective study in the United Kingdom identified no evidence of transmission among 150 health-care workers with parenteral or mucous-membrane exposure to blood or other body fluids, secretions, or excretions from patients with HIV infection [22].

Following needlestick injuries, one health-care worker contracted HBV but not HIV, and in another instance a health-care worker contracted cryptococcus but not HIV from patients infected with both [14]. This risk of infection by HIV and other blood-borne pathogens for which immunization is not available extends to all health-care workers exposed to blood, even those who have been immunized against HBV infection. Effective protection against blood-borne disease requires universal observation of common barrier precautions by all workers with potential exposure to blood, body fluids, and tissues [10,13].

HIV has been isolated from blood, semen, saliva, tears, urine, vaginal secretions, cerebrospinal fluid, breast milk, and amniotic fluid [10,23], but only blood and blood products, semen, vaginal secretions, and possibly breast milk (this needs to be confirmed) have been directly linked to transmission of HIV [10,13]. Contact with fluids such as saliva and tears has not been shown to result in infection [13-15]. Although other fluids have not been shown to transmit infection, all body fluids and tissues should be regarded as potentially contaminated by HBV or HIV, and treated as if they were infectious. Both HBV and HIV appear to be incapable of penetrating intact skin, but infection may result from infectious fluids coming into contact with mucous membranes or open wounds (including inapparent lesions) on the skin [14,16]. If a procedure involves the potential for skin contact with

blood or mucous membranes, then appropriate barriers to skin contact should be worn, e.g., gloves. Investigations of HBV risks associated with dental and other procedures that might produce particulates in air, e.g., centrifuging and dialysis, indicated that the particulates generated were relatively large droplets (spatter), and not true aerosols of suspended particulates that would represent a risk of inhalation exposure [24-26]. Thus, if there is the potential for splashes or spatter of blood or fluids, face shields or protective eyewear and surgical masks should be worn. Detailed protective measures for health-care workers have been addressed by the CDC [10,13,23,27-33]. These can serve as general guides for the specific groups covered, and for the development of comparable procedures in other working environments.

HIV infection is known to have been transmitted by organ transplants [34] and blood transfusions [35] received from persons who were HIV seronegative at the time of donation. Falsely negative serology can be due to improperly performed tests or other laboratory error, or testing in that "window" of time during which a recently infected person is infective but has not yet converted from seronegative to seropositive. (Detectable levels of antibodies usually develop within 6 to 12 weeks of infection [36]. A recent report [37] suggesting that this "window" may extend to 14 months is not consistent with other data, and therefore requires confirmation.) If all body fluids and tissues are treated as infectious, no additional level of worker protection will be gained by identifying seropositive patients or workers. Conversely, if worker protection and work practices were upgraded only following the return of positive HBV or HIV serology, then workers would be inadequately protected during the time required for testing. By producing a false sense of safety with "silent" HBV- or HIV-positive patients, a seronegative test may significantly reduce the level of routine vigilance and result in virus exposure. Furthermore, developing, implementing, and administering a program of routine testing would shift resources and energy away from efforts to assure compliance with infection control procedures. Therefore, routine screening of workers or patients for HIV antibodies will not substantially increase the level of protection for workers above that achieved by adherence to strict infection control procedures.

On the other hand, workers who have had parenteral exposure to fluids or tissues may wish to know whether their own antibody status converts from negative to positive. Such a monitoring program can lead to prophylactic interventions in the case of HBV infection, and CDC has published guidelines on pre- and post-exposure prophylaxis of viral hepatitis [1,2]. Future developments may also allow effective intervention in the case of HIV infection. For the present, post-exposure monitoring for HIV at least can release the affected worker from unnecessary emotional stress if infection did not occur, or allow the affected worker to protect sexual partners in the event infection is detected [10,36].

III. Summary:

The cumulative epidemiologic data indicate that transmission of HBV and HIV requires direct, intimate contact with or parenteral inoculation of blood and blood products, semen, or tissues [10,11,13,14,16,23]. The mere pres-

ence of, or casual contact with, an infected person cannot be construed as "exposure" to HBV or HIV. Although the theoretical possibility of rare or low-risk alternative modes of transmission cannot be totally excluded, the only documented occupational risks of HBV and HIV infection are associated with parenteral (including open wound) and mucous membrane exposure to blood and tissues [2,10,13,14,16]. Workers occupationally exposed to blood, body fluids, or tissues can be protected from the recognized risks of HBV and HIV infection by imposing barriers in the form of engineering controls, work practices, and protective equipment that are readily available, commonly used, and minimally intrusive.

IV. Recommendations:

General

"Exposure" (or "potential exposure") to HBV and HIV should be defined in terms of actual (or potential) skin, mucous membrane, or parenteral contact with blood, body fluids, and tissues. "Tissues" and "fluids" or "body fluids" should be understood to designate not only those materials from humans, but also potentially infectious fluids and tissues associated with laboratory investigations of HBV or HIV, e.g., organs and excreta from experimental animals, embryonated eggs, tissue or cell cultures and culture media, etc.

As the first step in determining what actions are required to protect worker health, every employer should evaluate all working conditions and the specific tasks that workers are expected to encounter as a consequence of employment. That evaluation should lead to the classification of work-related tasks to one of three categories of potential exposure (Table 1). These categories represent those tasks that require protective equipment to be worn during the task (Category I); tasks that do not require any protective equipment (Category III); and an intermediate grouping of tasks (Category II) that also do not require protective equipment, but that inherently include the predictable job-related requirement to perform Category I tasks unexpectedly or on short notice, so that these persons should have immediate access to some minimal set of protective devices. For example, law enforcement personnel or firefighters may be called upon to perform or assist in first aid or to be potentially exposed in some other way. This exposure classification applies to tasks rather than to individuals, who in the course of their daily activities may move from one exposure category to another as they perform various tasks.

For individual Category I and II tasks, engineering controls, work practices, and protective equipment should be selected after careful consideration, for each specific situation, of the overall risk associated with the task. Factors that should be included in that evaluation of risk include:

1. Type of body fluid with which there will or may be contact (e.g., blood is of greater concern than urine),
2. Volume of blood or body fluid likely to be encountered (e.g., hip replacement surgery can be very bloody while corneal transplantation is almost bloodless),

3. Probability of an exposure taking place (e.g., drawing blood will more likely lead to exposure to blood than will performing a physical examination),
4. Probable route of exposure (e.g., needlestick injuries are of greater concern than contact with soiled linens), and
5. Virus concentration in the fluid or tissue. The number of viruses per milliliter of fluid in research laboratory cultures may be orders of magnitude higher than in blood. Similarly, viruses have been less frequently found in fluids such as sweat, tears, urine, and saliva.

Engineering controls, work practices, and protective equipment appropriate to the task being performed are critical to minimize HBV and HIV exposure and to prevent infection. Adequate protection can be assured only if the appropriate controls and equipment are provided and all workers know the applicable work practices and how to properly use the required controls or protective equipment. Therefore, employers should establish a detailed work practices program that includes standard operating procedures (SOPs) for all tasks or work areas having the potential for exposure to fluids or tissues, and a worker education program to assure familiarity with work practices and the ability to use properly the controls and equipment provided.

It is essential for both the patient and the health-care worker to be fully aware of the reasons for the preventive measures used. The health-care worker may incorrectly interpret the work practices and protective equipment as signifying that a task is unsafe. The patient may incorrectly interpret the work practices or protective garb as evidence that the health-care

TABLE 1. EXPOSURE CATEGORIES

CATEGORY I. Tasks That Involve Exposure To Blood, Body Fluids, Or Tissues.

All procedures or other job-related tasks that involve an inherent potential for mucous membrane or skin contact with blood, body fluids, or tissues, or a potential for spills or splashes of them, are Category I tasks. Use of appropriate protective measures should be required for every employee engaged in Category I tasks.

CATEGORY II. Tasks That Involve No Exposure To Blood, Body Fluids, Or Tissues, But Employment May Require Performing Unplanned Category I Tasks.

The normal work routine involves no exposure to blood, body fluids, or tissues, but exposure or potential exposure may be required as a condition of employment. Appropriate protective measures should be readily available to every employee engaged in Category II tasks.

CATEGORY III. Tasks That Involve No Exposure To Blood, Body Fluids, Or Tissues, And Category I Tasks Are Not A Condition Of Employment.

The normal work routine involves no exposure to blood, body fluids, or tissues (although situations can be imagined or hypothesized under which anyone, anywhere, might encounter potential exposure to body fluids). Persons who perform these duties are not called upon as part of their employment to perform or assist in emergency medical care or first aid or to be potentially exposed in some other way. Tasks that involve handling of implements or utensils, use of public or shared bathroom facilities or telephones, and personal contacts such as handshaking are Category III tasks.

provider knows or believes the patient is infected with HBV or HIV. Therefore, worker education programs should strive to allow workers (and to the extent feasible, the clients or patients) to recognize the routine use of appropriate work practices and protective equipment as prudent steps that protect the health of all.

If the employer determines that Category I and II tasks do not exist in the workplace, then no specific personal hygiene or protective measures are required. However, these employers should ensure that workers are aware of the risk factors associated with transmission of HBV and HIV so that they can recognize situations which pose increased potential for exposure to HBV or HIV (Category I tasks) and know how to avoid or minimize personal risk. A comparable level of education is necessary for all citizens. Educational materials such as the Surgeon General's Report can provide much of the needed information [12,38].

If the employer determines that work-related Category I or II tasks exist, then the following procedures should be implemented.

Administrative

The employer should establish formal procedures to ensure that Category I and II tasks are properly identified, SOPs are developed, and employees who must perform these tasks are adequately trained and protected. If responsibility for implementation of these responsibilities is delegated to a committee, it should include both management and worker representatives. Administrative activities to enhance worker protection include:

1. Evaluating the workplace to:
 - a. Establish category of risk classifications for all routine and reasonably anticipated job-related tasks.
 - b. Identify all workers whose employment requires performance of Category I or II tasks.
 - c. Determine for identified Category I or II tasks those body fluids to which workers most probably will be exposed and the potential extent and route of exposure.
2. Developing, or supervising the development of, Standard Operating Procedures (SOPs) for each Category I and II task. These SOPs should include mandatory work practices and protective equipment for each Category I and II task.
3. Monitoring the effectiveness of work practices and protective equipment. This includes:
 - a. Surveillance of the workplace to ensure that required work practices are observed and that protective clothing and equipment are provided and properly used.
 - b. Investigation of known or suspected parenteral exposures to body fluids or tissues to establish the conditions surrounding the exposure and to improve training, work practices, or protective equipment to prevent a recurrence

Training and Education

The employer should establish an initial and periodic training program for all employees who perform Category I and II tasks. No worker should engage in any Category I or II task before receiving training pertaining to the SOPs, work practices, and protective equipment required for that task. The training program should ensure that all workers:

1. Understand the modes of transmission of HBV and HIV.
2. Can recognize and differentiate Category I and II tasks.
3. Know the types of protective clothing and equipment generally appropriate for Category I and II tasks, and understand the basis for selection of clothing and equipment.
4. Are familiar with appropriate actions to take and persons to contact if unplanned Category I tasks are encountered.
5. Are familiar with and understand all the requirements for work practices and protective equipment specified in SOPs covering the tasks they perform.
6. Know where protective clothing and equipment is kept, how to use it properly, and how to remove, handle, decontaminate, and dispose of contaminated clothing or equipment.
7. Know and understand the limitations of protective clothing and equipment. For example, ordinary gloves offer no protection against needlestick injuries. Employers and workers should be on guard against a sense of security not warranted by the protective equipment being used.
8. Know the corrective actions to take in the event of spills or personal exposure to fluids or tissues, the appropriate reporting procedures, and the medical monitoring recommended in cases of suspected parenteral exposure.

Engineering Controls

Whenever possible, engineering controls should be used as the primary method to reduce worker exposure to harmful substances. The preferred approach in engineering controls is to use, to the fullest extent feasible, intrinsically safe substances, procedures, or devices. Substitution of a hazardous procedure or device with one that is less risky or harmful is an example of this approach, e.g., a laser scalpel reduces the risk of cuts and scrapes by eliminating the necessity to handle the conventional scalpel blade.

Isolation or containment of the hazard is an alternative engineering control technique. Disposable, puncture-resistant containers for used needles, blades, etc., isolate cut and needlestick injury hazards from the worker. Glove boxes, ventilated cabinets, or other enclosures for tissue homogenizers, sonicators, vortex mixers, etc. serve not only to isolate the hazard, but also to contain spills or splashes and prevent spatter and mist from reaching the worker.

After the potential for exposure has been minimized by engineering controls, further reductions can be achieved by work practices and, finally, personal protective equipment.

Work Practices

For all identified Category I and II tasks, the employer should have written, detailed Standard Operating Procedures (SOPs). All employees who perform Category I or II tasks should have ready access to the SOPs pertaining to those tasks.

1. Work practices should be developed on the assumption that all body fluids and tissues are infectious. General procedures to protect health-care workers against HBV or HIV transmission have been published elsewhere [1, 2, 23,28-33]. Each employer with Category I and II tasks in the workplace should incorporate those general recommendations, as appropriate, or equivalent procedures into work practices and SOPs. The importance of handwashing should be emphasized.
2. Work practices should include provision for safe collection of fluids and tissues and for disposal in accordance with applicable local, state, and federal regulations. Provision must be made for safe removal, handling, and disposal or decontamination of protective clothing and equipment, soiled linens, etc.
3. Work practices and SOPs should provide guidance on procedures to follow in the event of spills or personal exposure to fluids or tissues. These procedures should include instructions for personal and area decontamination as well as appropriate management or supervisory personnel to whom the incident should be reported.
4. Work practices should provide specific and detailed procedures to be observed with sharp objects, e.g., needles, scalpel blades. Puncture-resistant receptacles must be readily accessible for depositing these materials after use. These receptacles must be clearly marked and specific work practices provided to protect personnel responsible for disposing of them or processing their contents for reuse.

Personal Protective Equipment

Based upon the fluid or tissue to which there is potential exposure, the likelihood of exposure occurring, the potential volume of material, the probable route of exposure, and overall working conditions and job requirements, the employer should provide and maintain personal protective equipment appropriate to the specific requirements of each task.

For workers performing Category I tasks, a required minimum array of protective clothing or equipment should be specified by pertinent SOPs. All Category I tasks do not involve the same type or degree of risk, and therefore all do not require the same kind or extent of protection. Specific combinations of clothing and equipment must be tailored to specific tasks. Minimum levels of protection for Category I tasks in most cases would include use of appropriate gloves. If there is the potential for splashes, protective eyewear or face shields should be worn. Paramedics responding to an auto accident might protect against cuts on metal and glass by wearing gloves or gauntlets that are both puncture-resistant and impervious to blood. If the conditions of exposure include the potential for clothing becoming soaked with blood, protective outer garments such as impervious coveralls should be worn.

For workers performing Category II tasks, there should be ready access to appropriate protective equipment, e.g., gloves, protective eyewear, or surgi-

cal masks, specified in pertinent SOPs. Workers performing Category II tasks need not be wearing protective equipment, but they should be prepared to put on appropriate protective garb on short notice.

Medical

In addition to any health-care or surveillance required by other rules, regulations, or labor-management agreement, the employer should make available at no cost to the worker:

1. Voluntary HBV immunization for all workers whose employment requires them to perform Category I tasks and who test negative for HBV antibodies. Detailed recommendations for protecting health-care workers from viral hepatitis have been published by the CDC [1]. These recommendations include procedures for both pre- and post-exposure prophylaxis, and should be the basis for the routine approach by management to the prevention of occupational hepatitis B.
2. Monitoring, at the request of the worker, for HBV and HIV antibodies following known or suspected parenteral exposure to blood, body fluids, or tissues. This monitoring program must include appropriate provisions to protect the confidentiality of test results for all workers who may elect to participate.
3. Medical counseling for all workers found, as a result of the monitoring described above, to be seropositive for HBV or HIV. Counseling guidelines have been published by the Public Health Service [1, 2, 36].

Recordkeeping

If any employee is required to perform Category I or II tasks, the employer should maintain records documenting:

1. The administrative procedures used to classify job tasks. Records should describe the factors considered and outline the rationale for classification.
2. Copies of all SOPs for Category I and II tasks, and documentation of the administrative review and approval process through which each SOP passed.
3. Training records, indicating the dates of training sessions, the content of those training sessions along with the names of all persons conducting the training, and the names of all those receiving training.
4. The conditions observed in routine surveillance of the workplace for compliance with work practices and use of protective clothing or equipment. If noncompliance is noted, the conditions should be documented along with corrective actions taken.
5. The conditions associated with each incident of mucous membrane or parenteral exposure to body fluids or tissue, an evaluation of those conditions, and a description of any corrective measures taken to prevent a recurrence or other similar exposure.

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For further information call: National OSHA Information Office, (202) 523-8148.

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March 31, 1992

Rep. Ron Wyden, Chair
U.S. House of Representatives
Committee on Small Business
Subcommittee on Regulation, Business Opportunities, and Energy
B-363 Rayburn House Office Building
Washington, D.C. 20515-6318

Dear Rep. Wyden

As we indicated in testimony before your subcommittee on February 7, 1992, the American Hospital Association (AHA) and its member hospitals strongly support the development and implementation of effective new technologies to reduce injuries from needlesticks and other sharp instruments. AHA's witness Mr. William Johnson, CEO of the University of New Mexico Hospital in Albuquerque, New Mexico and chair of the association's current and past ad hoc committees on HIV infection, outlined his thoughts about an effective hospital-based needlestick prevention program. His model includes four elements:

- a defined infection control program;
- employee education about bloodborne diseases and ways to reduce occupational risk of transmission;
- strong senior management commitment to improving needle safety;
- ongoing institutional evaluation of newly available safety devices.

You asked that the AHA provide information about the operation of such programs by our member hospitals.

Overview of Available Information on Hospital-based Needle Safety Programs

AHA has not specifically surveyed our member hospitals about their operation of a needle safety program like that described above. Currently, no national data base on hospital-based needle safety programs exists. However, information that bears on aspects of the question asked by the subcommittee are available from a variety of sources.

Below we provide information from the Joint Commission on Accreditation of Healthcare Organizations (the Joint Commission) about hospitals' operation of infection control programs. In addition, we discuss information obtained from an Occupational Health and Safety Administration (OSHA) survey about education programs to inform health care workers about bloodborne diseases and ways to reduce the risk of occupational transmission of these infections.

We also include information from the most recent edition of the Joint Commission's *Hospital Accreditation Statistics* about management's support for quality assurance activities which may include needle safety. We also discuss Joint Commission data on the operation of equipment management programs for assessing and controlling the clinical and physical risks of equipment used for the diagnosis, treatment, monitoring, and care of patients. Evaluation of new safe needle devices may be included as an element of these equipment management programs. In an attachment to this letter, we have provided the full text of relevant standards from the Joint Commission's *Accreditation Manual for Hospitals*.

We also include some examples of hospital programs for evaluation of new devices. Finally, we provide an overview of additional planned AHA activities to assist our member hospitals in evaluating and adopting effective new technologies. Also attached to this letter is an up-to-date listing of resources AHA has already developed and disseminated to assist its member hospitals in further improving health care worker safety, many of which address needle safety and implementation of safer needle devices.

Operation of Infection Control Programs

Hospitals that comply with voluntary standards of the Joint Commission have hospital-wide programs for the surveillance, prevention, and control of infection. In order to meet Joint Commission standards, hospitals must have written policies and procedures for infection surveillance, prevention, and control for all patient care departments. In addition, patient care support departments and services (e.g., central services, housekeeping, and laundry services) are involved in efforts to prevent and control infections. Hospital infection control programs are overseen by

multidisciplinary committee and management responsibility for infection control activities is assigned to an experienced infection control practitioner.

The Joint Commission surveys hospitals to determine their level of compliance with these standards, using a five-point rating scale (see attachment for description of the rating scale). The most recent Joint Commission data indicate that 89.8% of hospitals surveyed in the 1987-1989 period consistently met all or most major provisions of the infection control standard.

Educating Employees About the Occupational Risk of BloodBorne Diseases and Ways to Minimize Such Risk

Worker education has always been an important component of hospital infection control activities. Results from an unpublished random survey conducted in November 1989 by OSHA demonstrate that nearly all hospitals provide education and training about the prevention of occupational exposure to bloodborne diseases to all employees with potential occupational exposure. Such training is provided to patient care staff by 99% of hospitals; to laboratory employees by 96% of hospitals; and to service employees (e.g., housekeeping, laundry, etc.) by 99% of hospitals. For most hospital employees, training is provided prior to job assignment or performance of any job-related tasks.

As part of its bloodborne pathogens standard which becomes effective on March 6, 1992, OSHA now mandates that hospitals provide education about occupational blood and body fluid exposures and safety to all employees with potential occupational exposure. Annual retraining is also required. Training must be provided at no cost to the employee, during regular working hours, and at a location reasonably accessible to all employees. Appropriate training records which include the date of the training session, a summary of the content of the program, the names and qualifications of those conducting the training, and the names and job titles of all employees in attendance at the training session must be maintained for three years. OSHA's 1989 survey, however, clearly indicates that hospitals responded to this critical issue well before the issuance of final regulatory guidelines.

Management Involvement in Quality Assurance

Hospitals that meet Joint Commission standards also must demonstrate governing body and management support for ongoing quality assurance programs. Quality assurance programs allow hospitals to objectively and systematically monitor, evaluate, and improve the quality and appropriateness of patient care and

clinical performance. Improving the safety of medical technology such as needle devices may be part of ongoing quality assurance efforts.

The most recent data from the Joint Commission indicate that 82.4 percent of hospitals surveyed during the 1987-1989 period consistently met all or most major provisions of the quality assurance standard. Hospital efforts to comply with this standard have improved significantly from 1986 to 1989. Of the hospitals surveyed in both 1986 and 1989, a larger percentage consistently met all major provisions of the standard in 1989 (84.8% in 1989 compared with 73.6% in 1986).

Operation of Equipment Management Programs

Hospitals that meet Joint Commission standards must also establish an equipment management program designed to assess and control on an ongoing basis the clinical and physical risks of equipment used for the diagnosis, treatment, monitoring, and care of patients. Safe needle devices may be evaluated through these equipment management programs. The most recent Joint Commission data indicate that 66.2% of hospitals surveyed in the 1987-1989 period consistently met all major or most provisions of the equipment management standard.

Approximately 33 percent of hospitals demonstrated a level of compliance with this standard that was less than satisfactory. The Joint Commission, however, points out that this standard was substantially revised in 1989 to increase management's responsibilities for overseeing the patient care environment. During the first year in which the revised standards were in effect, many hospitals were not fully able to implement equipment management systems comparable to those required under the revised standard.

According to the Joint Commission, this is a common experience with new standards and requirements. In fact, the Joint Commission expects a lower level of compliance with new or revised standards during the initial years of their release. Standards are specifically developed to stimulate hospitals to achieve higher levels of performance over time. The Joint Commission recognizes that few hospitals will be in a position to fully comply with standards at first. In the Joint Commission's experience, hospitals demonstrate progressive improvements in compliance.

Examples of Hospital Programs for New Product Evaluation

Below are some examples of hospital programs for new product evaluation.

- St. Elizabeth's Hospital--Boston, MA. St. Elizabeth's Hospital has a multidisciplinary Value Analysis Committee which evaluates all new product lines that have significant budget and patient care implications. The Committee forwards its recommendations directly to the hospital's administration. In addition, nursing staff may adopt new products without formal Committee approval if these products do not have significant budgetary or patient care impacts.
- Illinois Masonic Medical Center--Chicago, IL. Through contacts with vendors, the Assistant Administrator for Operations identifies new products. Initial assessment includes safety and maintenance considerations, infection control implications, potential problems of actually using the device in a clinical setting (including its susceptibility for improper use), staff training needs, and the costs of utilizing the device. After this initial assessment, new devices will be tested on a specific floor of the hospital. A multidisciplinary Product Evaluation Committee makes a final decision on implementation.
- LAC-Harbor UCLA--Los Angeles, CA. The hospital has a nursing products evaluation committee, largely composed of nursing staff with consultation from physicians, infection control, materials management, and other relevant departments. Products are evaluated in an area of low patient volume for effectiveness and ease of use. The committee makes final recommendations to hospital administration. The hospital is currently investigating needle disposal systems and safe needle devices in response to OSHA regulations.
- Johnson City Specialty Hospital--Johnson City, TN. The hospital has a Product Standardization Committee with representation from a variety of areas within the hospital. This committee tests all new products for a specified period of time and then assesses the costs and benefits of utilizing the new product. The committee makes a final determination about adoption of the product once costs and benefits have been determined.

Overview of AHA Plans for Additional Membership Assistance to Facilitate Adoption of Safer Needle Devices

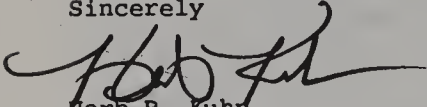
AHA continues to assist its member hospitals in their efforts to identify, evaluate, and adopt new, safer technologies. In addition to the resources relating to worker safety and adoption of safer needle technologies that AHA has already developed (described in an attachment), AHA plans include:

- **Publicizing upcoming conferences.** Through its various publications, including *AHA News* and *Hospitals* magazine, AHA will publicize upcoming conferences and workshops concerned with new safer needle devices. These conferences and workshops are designed to educate hospitals and their employees about needlestick prevention, identifying new technologies, methods for new product evaluation, and various regulatory requirements for preventing exposure to bloodborne diseases.
- **Development of a Videotape Program on Needle Safety Devices.** This videotape will feature a needle safety expert panel discussion taped at the May 19-20 Needlestick Prevention Conference in Charlottesville, VA.
- **Special Member Briefings on Safe Needle Devices.** AHA expects to issue a special briefing to member hospitals in May. While the specific content of this briefing has not been finalized, it will include an overview of needle safety issues, needlestick injury data collection tools, new product evaluation tools, and case studies of successful hospital-based needle safety device evaluation programs. An additional briefing will follow later in the year.
- **Teleconference on Needle Safety Devices.** A September date is planned for this teleconference on needle safety devices. Content has not been finalized.
- **Periodic Meetings of AHA's Needlestick Work Group.** AHA has convened a special advisory panel consisting of national experts on needle safety to continually advise us on the latest developments in the area of needle safety.
- **Program on Safe Needle Devices for Health Care Risk Managers.** A round table discussion on safe needle devices will be included in the November annual meeting program for the American Society of Healthcare Risk Managers. A member of AHA's Needlestick Work Group has already agreed to chair this program.

- **Periodic Updates on Newly Available Safe Needle Devices.** Information on newly available safer needle technologies will be provided periodically through existing Association periodicals, such as our series on technology.

If you have additional questions about the above comments, please contact Lawrence Hughes (312/280-6735) or Karen Kroc (312/280-4437) of our Chicago office or Carla Luggiero (202/626-2333) of our Washington office.

Sincerely



Herb B. Kuhn
Vice President
Congressional and Executive Branch Relations

AHA ACTIVITIES PROMOTING HEALTH CARE WORKER SAFETY

This listing includes all programs that the AHA has produced or been involved with which promote health care worker safety. Bolded programs reflect those which address sharps safety and safe needle technologies.

Publications

Management of HIV Infection in the Hospital - Recommendations of the technical panel of infections within hospitals - 3rd edition; revised 1988. Previous editions 1983, 1986

Universal Precautions - policies, procedures, and resources; AHA publication, 1991

Right-to-Know for Hospital Workers, published 1991

Video Programs

Is It Worth the Risk? Safe Handling of Blood and Body Fluids, 1987.

Hazardous Materials: MSDS and Warning Labels, 1987

Working Together: Needlestick Prevention. Developed in conjunction with a grant from OSHA, 1989. Contains video and print material.

Under Surveillance...Detecting Environmental Hazards, 1990

Universal Precautions: Multimedia Building Blocks for Prevention and Compliance Training, 1990. Contains video (Is It Worth the Risk), slides and print material.

AHA Teleconferences

1987 **AIDS: Protecting Hospital Employees**

1989 **OSHA's Bloodborne Pathogen Standard: Preparing for the new rule. New technologies regarding needle safety were demonstrated as part of this program.**

1991 **AHA Video Update: OSHA's Final Bloodborne Pathogen**

Documents to Member Hospitals

August 1989- Dear Colleague mailing. Technical briefing prepared by Quality Control and sent to hospitals as an overview of those occupational health and safety regulations most pertinent to hospital safety programs. Mentions but does not discuss the bloodborne pathogen rule as this had been covered separately.

February 1992- Special Briefing on OSHA final rule to hospitals.

Consultations

1990 AHA invited to SEIU meeting, "Controlling Needlestick Injuries: A National Meeting". M. Hardy attended.

1990 AHA staff (Gina Pugliese--Infection Control) invited to serve as faculty on N.Y. State program on worker protection. Gina sat on panel with SEIU and OSHA at this same meeting.

1989/1990 Gina Pugliese served as faculty at OSHA's Biohazard Training Course for Compliance Officers, "Bloodborne Pathogen Risks in Health Care Settings and Methods to Reduce Risks".

12/90 Meeting between Gina Pugliese, Terry Montgomery (ASHMM) and June Fisher, San Francisco General Hospital Department of Occupational Safety, regarding distributing information to material managers about safe needle devices and the newer technologies.

2/92 Formation of the "Needlestick Work Group" (Gina Pugliese responsible for convening group) to advise the AHA on needle safety. The work group is comprised of national experts in the field of needle safety.

Miscellaneous

Monthly engagements to speak with various health care groups both local and national meetings on topics which include: occupational risks of bloodborne infections, risk reductions strategies, universal precautions, sharps safety, and OSHA.

June 1989 AHA News Viewpoint "Training, new designs needed to cut needlestick injuries", by Gina Pugliese.

3.11.92

Quality Assurance (QA)

Standard

Circle One

- QA.1** There is an ongoing quality assurance program designed to objectively and systematically monitor and evaluate the quality and appropriateness of patient care, pursue opportunities to improve patient care, and resolve identified problems.*

1 2 3 4 5 NA

Required Characteristics

- QA.1.1** The governing body strives to assure quality patient care by requiring and supporting the establishment and maintenance of an effective hospitalwide quality assurance program.*

1 2 3 4 5 NA

- QA.1.2** Clinical and administrative staffs monitor and evaluate the quality and appropriateness of patient care and clinical performance, resolve identified problems, and report information to the governing body that the governing body needs to assist it in fulfilling its responsibility for the quality of patient care.*

1 2 3 4 5 NA

- QA.1.3** There is a written plan for the quality assurance program that describes the program's objectives, organization, scope, and mechanisms for overseeing the effectiveness of monitoring, evaluation, and problem-solving activities.*

1 2 3 4 5 NA

- QA.1.4** There are operational linkages between the risk management functions related to the clinical aspects of patient care and safety and quality assurance functions.*

1 2 3 4 5 NA

- QA.1.5** Existing information from risk management activities that may be useful in identifying clinical problems and/or opportunities to improve the quality of patient care is accessible to the quality assurance function.*

1 2 3 4 5 NA

*The asterisked items are key factors in the accreditation decision process. For an explanation of the use of the key factors, see "Using the Manual," page xi.

Standard**Circle One**

- QA.2** The scope of the quality assurance program includes at least the activities listed in Required Characteristics QA.2.1 through QA.2.5.3 and described in other chapters of this *Manual*.

1 2 3 4 5 NA

Required Characteristics

- QA.2.1** The following medical staff functions are performed:

QA.2.1.1 The monitoring and evaluation of the quality and appropriateness of patient care and the clinical performance of all individuals with clinical privileges through

QA.2.1.1.1 monthly meetings of clinical departments or major clinical services (or the medical staff, for a nondepartmentalized medical staff) to consider findings from the ongoing monitoring activities of the medical staff ("Medical Staff" Standard MS.3, Required Characteristics MS.3.7 and MS.3.7.1);*

1 2 3 4 5 NA

QA.2.1.1.2 surgical case review ("Medical Staff" Standard MS.6, Required Characteristic MS.6.1.2);*

1 2 3 4 5 NA

QA.2.1.1.3 drug usage evaluation ("Medical Staff" Standard MS.6, Required Characteristic MS.6.1.3);*

1 2 3 4 5 NA

QA.2.1.1.4 the medical record review function ("Medical Staff" Standard MS.6, Required Characteristic MS.6.1.4);*

1 2 3 4 5 NA

QA.2.1.1.5 blood usage review ("Medical Staff" Standard MS.6, Required Characteristic MS.6.1.5);* and

1 2 3 4 5 NA

QA.2.1.1.6 the pharmacy and therapeutics function ("Medical Staff" Standard MS.6, Required Characteristic MS.6.1.6).*

1 2 3 4 5 NA

- QA.2.2** The quality and appropriateness of patient care, including that provided to specific age groups, in at least the following services are monitored and evaluated:*

QA.2.2.1 Alcoholism and other drug dependence services, when provided (Standard AL.4);

1 2 3 4 5 NA

QA.2.2.2 Diagnostic radiology services (Standard DR.4);

1 2 3 4 5 NA

QA.2.2.3 Dietetic services (Standard DT.7);

1 2 3 4 5 NA

QA.2.2.4 Emergency services (Standard ER.9);

1 2 3 4 5 NA

QA.2.2.5 Hospital-sponsored ambulatory care services (Standard HO.7);

1 2 3 4 5 NA

QA.2.2.6 Nuclear medicine services (Standard NM.4);

1 2 3 4 5 NA

QA.2.2.7 Nursing services (Standard NR.8);

1 2 3 4 5 NA

QA.2.2.8 Pathology and medical laboratory services (Standard PA.7);

1 2 3 4 5 NA

QA.2.2.9 Pharmaceutical services (Standard PH.6);

1 2 3 4 5 NA

*The asterisked items are key factors in the accreditation decision process. For an explanation of the use of the key factors, see "Using the Manual," page xi.

	Circle One
QA.2.2.10 Physical rehabilitation services (Standard RH.4);	1 2 3 4 5 NA
QA.2.2.11 Radiation oncology services (Standard RA.4);	1 2 3 4 5 NA
QA.2.2.12 Respiratory care services (Standard RP.6);	1 2 3 4 5 NA
QA.2.2.13 Social work services (Standard SO.5);	1 2 3 4 5 NA
QA.2.2.14 Special care units (Standard SP.6); and	1 2 3 4 5 NA
QA.2.2.15 Surgical and anesthesia services (Standard SA.4).	1 2 3 4 5 NA
QA.2.3 The following hospitalwide functions are performed:*	
QA.2.3.1 Infection control (Standards IC.1 and IC.2);	1 2 3 4 5 NA
QA.2.3.2 Utilization review (Standard UR.1); and	1 2 3 4 5 NA
QA.2.3.3 Review of accidents, injuries, patient safety, and safety hazards ("Plant, Technology, and Safety Management" Standard PL.1, Required Characteristics PL.1.4.2, PL.1.4.3, and PL.1.7).	1 2 3 4 5 NA
QA.2.4 The quality of patient care and the clinical performance of those individuals who are not permitted by the hospital to practice independently are monitored and evaluated through the mechanisms described in Required Characteristics QA.2.1 through QA.2.3.3 or through other mechanisms implemented by the hospital ("Governing Body" Standard GB.1, Required Characteristic GB.1.15).*	1 2 3 4 5 NA
QA.2.5 Relevant findings from the quality assurance activities listed in Required Characteristics QA.2.1 through QA.2.3.3 are considered as part of	
QA.2.5.1 the reappraisal/reappointment of medical staff members ("Medical Staff" Standard MS.5, Required Characteristic MS.5.3.1.5);*	1 2 3 4 5 NA
QA.2.5.2 the renewal or revision of the clinical privileges of individuals who practice independently ("Medical Staff" Standard MS.5, Required Characteristic MS.5.3.1);* and	1 2 3 4 5 NA
QA.2.5.3 the mechanisms used to appraise the competence of all those individuals not permitted by the hospital to practice independently ("Governing Body" Standard GB.1, Required Characteristic GB.1.15).*	1 2 3 4 5 NA

Preamble

The monitoring and evaluation process is designed to help health care organizations effectively use their quality assurance resources by focusing on high-priority quality-of-care issues. In order to accomplish this, the process involves

- identification of the most important aspects of the care (for example, procedures or treatments) the organization (or department or service) provides;*
- use of measurable indicators to systematically monitor these aspects of care in an ongoing way;*

*The asterisked items are key factors in the accreditation decision process. For an explanation of the use of the key factors, see "Using the Manual," page xi.

- evaluation of the care when thresholds are reached in the monitoring process to identify opportunities for improvement or problems in the quality and appropriateness of care; and
- taking actions to improve care or solve problems, and evaluation of the effectiveness of those actions.

Because the use of indicators to monitor important aspects of care involves the collection and aggregation of data about a series of events or activities, the monitoring and evaluation process can be used to identify trends or patterns of care that may not be evident when only case-by-case review is performed. Indicators can also be used to identify important single events that may represent poor-quality care. Whether focused on patterns or single events, the use of indicators helps to efficiently identify situations in which case review (for example, peer review) is most likely to identify either opportunities to improve care or correctable deficiencies in care. Although the monitoring and evaluation process will not identify every case of substandard care, it does help the organization identify situations on which its attention could be most productively focused.

The process is composed of the following ten steps:

1. Assign responsibility for monitoring and evaluation activities;
2. Delineate the scope of care provided by the organization;
3. Identify the most important aspects of care provided by the organization;
4. Identify indicators (and appropriate clinical criteria) for monitoring the important aspects of care;
5. Establish thresholds (levels, patterns, trends) for the indicators that trigger evaluation of the care;
6. Monitor the important aspects of care by collecting and organizing the data for each indicator;
7. Evaluate care when thresholds are reached in order to identify either opportunities to improve care or problems;
8. Take actions to improve care or to correct identified problems;
9. Assess the effectiveness of the actions and document the improvement in care; and
10. Communicate the results of the monitoring and evaluation process to relevant individuals, departments, or services and to the organizationwide quality assurance program.

Standard QA.3 and Required Characteristics QA.3.1 through QA.3.2.8 address the second through tenth steps of this process.

Standard

Circle One

- QA.3** Monitoring and evaluation activities, including those described in Standard QA.2, Required Characteristics QA.2.1 through QA.2.4, reflect the activities described in Required Characteristics QA.3.1 through QA.3.2.8.*

1 2 3 4 5 NA

*The asterisked items are key factors in the accreditation decision process. For an explanation of the use of the key factors, see "Using the Manual," page xi.

Required Characteristics**Circle One**

- QA.3.1** There is a planned, systematic, and ongoing process for monitoring, evaluating, and improving the quality and appropriateness of care provided to patients.* 1 2 3 4 5 NA
- QA.3.1.1 This process is designed to effectively utilize quality assurance resources to
- QA.3.1.1.1 identify and take opportunities to make important improvements in patient care; and 1 2 3 4 5 NA
- QA.3.1.1.2 identify and correct problems that have the greatest (or an important) effect on patient care. 1 2 3 4 5 NA
- QA.3.1.2 The monitoring process is designed to identify
- QA.3.1.2.1 patterns or trends in care that warrant evaluation; and/or 1 2 3 4 5 NA
- QA.3.1.2.2 important single clinical events in the process or outcome of care that also warrant evaluation. 1 2 3 4 5 NA
- QA.3.1.3 The evaluation is designed to
- QA.3.1.3.1 determine the presence or absence of an opportunity to improve, or a problem in the quality and/or appropriateness of care; and 1 2 3 4 5 NA
- QA.3.1.3.2 determine how to improve care or correct the problem. 1 2 3 4 5 NA
- QA.3.2** The monitoring and evaluation process has the characteristics described in Required Characteristics QA.3.2.1 through QA.3.2.8.* 1 2 3 4 5 NA
- QA.3.2.1 Those aspects of care that are most important to the health and safety of the patients served are identified.* 1 2 3 4 5 NA
- QA.3.2.1.1 These important aspects of care are those that
- QA.3.2.1.1.1 occur frequently or affect large numbers of patients; 1 2 3 4 5 NA
- QA.3.2.1.1.2 place patients at risk of serious consequences or of deprivation of substantial benefit when 1 2 3 4 5 NA
- QA.3.2.1.1.2.1 the care is not provided correctly; or 1 2 3 4 5 NA
- QA.3.2.1.1.2.2 the care is not provided when indicated; or 1 2 3 4 5 NA
- QA.3.2.1.1.2.3 the care is provided when not indicated; and/or 1 2 3 4 5 NA
- QA.3.2.1.1.3 tend to produce problems for patients or staff. 1 2 3 4 5 NA
- QA.3.2.2 Indicators are identified to monitor the quality and appropriateness of important aspects of care.* 1 2 3 4 5 NA
- QA.3.2.2.1 The indicators are related to the quality and/or appropriateness of care and may include clinical criteria (sometimes called "standards, guidelines or parameters of care or practice"). 1 2 3 4 5 NA
- QA.3.2.2.1.1 These indicators are

*The asterisked items are key factors in the accreditation decision process. For an explanation of the use of the key factors, see "Using the Manual," page xi.

	Circle One
QA.3.2.2.1.1 objective;	1 2 3 4 5 NA
QA.3.2.2.1.1.2 measurable; and	1 2 3 4 5 NA
QA.3.2.2.1.1.3 based on current knowledge and clinical experience.	1 2 3 4 5 NA
QA.3.2.2.1.2 These indicators reflect structures of care (for example, resources), processes of care (for example, procedures, techniques), or outcomes of care (for example, complication rates).	1 2 3 4 5 NA
QA.3.2.3 Data are collected for each indicator.*	1 2 3 4 5 NA
QA.3.2.3.1 The frequency of data collection for each indicator and the sampling of events or activities are related to	
QA.3.2.3.1.1 the frequency of the event or activity monitored;	1 2 3 4 5 NA
QA.3.2.3.1.2 the significance of the event or activity monitored; and	1 2 3 4 5 NA
QA.3.2.3.1.3 the extent to which the important aspect of care monitored by the indicator has been demonstrated to be problem-free.	1 2 3 4 5 NA
QA.3.2.4 The data collected for each indicator are organized so that situations in which an evaluation of the quality or appropriateness of care is indicated are readily identified.*	1 2 3 4 5 NA
QA.3.2.4.1 Such evaluations are prompted by	
QA.3.2.4.1.1 important single clinical events; and	1 2 3 4 5 NA
QA.3.2.4.1.2 patterns of care or outcomes that are at variance with predetermined levels of care or outcomes (sometimes called "thresholds for evaluation").	1 2 3 4 5 NA
QA.3.2.5 When initiated, the evaluation of an important aspect of care	
QA.3.2.5.1 includes analysis of trends and patterns in the data collected on the indicators;*	1 2 3 4 5 NA
QA.3.2.5.2 includes review by peers when analysis of the care provided by a practitioner is undertaken; and*	1 2 3 4 5 NA
QA.3.2.5.3 identifies opportunities to improve, or problems in, the quality and/or appropriateness of care.*	1 2 3 4 5 NA
QA.3.2.6 When an important opportunity to improve, or problem in, the quality and/or appropriateness of care is identified,*	1 2 3 4 5 NA
QA.3.2.6.1 action is taken to improve the care or to correct the problem; and*	1 2 3 4 5 NA
QA.3.2.6.2 the effectiveness of the action taken is assessed through continued monitoring of the care.*	1 2 3 4 5 NA
QA.3.2.7 The findings, conclusions, recommendations, actions taken, and results of the actions taken are	

*The asterisked items are key factors in the accreditation decision process. For an explanation of the use of the key factors, see "Using the Manual," page xi.

Circle One

QA.3.2.7.1 documented; and*

1 2 3 4 5 NA

QA.3.2.7.2 reported through established channels.*

1 2 3 4 5 NA

QA.3.2.8 As part of the annual appraisal of the hospital's quality assurance program, the effectiveness of the monitoring and evaluation process is assessed.*

1 2 3 4 5 NA

Standard

QA.4 The administration and coordination of the hospital's overall quality assurance program are designed to assure that the activities described in Required Characteristics QA.4.1 through QA.4.5 are undertaken.*

1 2 3 4 5 NA

Required Characteristics

QA.4.1 Each of the monitoring and evaluation activities outlined in Standards QA.2 and QA.3 is performed appropriately and effectively.*

1 2 3 4 5 NA

QA.4.2 Necessary information is communicated among departments/services when problems or opportunities to improve patient care involve more than one department/service.*

1 2 3 4 5 NA

QA.4.3 The status of identified problems is tracked to assure improvement or resolution.*

1 2 3 4 5 NA

QA.4.4 Information from departments/services and the findings of discrete quality assurance activities are used to detect trends, patterns of performance, or potential problems that affect more than one department/service.*

1 2 3 4 5 NA

QA.4.5 The objectives, scope, organization, and effectiveness of the quality assurance program are evaluated at least annually and revised as necessary.*

1 2 3 4 5 NA

*The asterisked items are key factors in the accreditation decision process. For an explanation of the use of the key factors, see "Using the Manual," page xi.

The "Quality Assurance" chapter became effective for accreditation purposes on January 1, 1985.

The required characteristics concerning risk management (QA.1.4 and QA.1.5) and the revision to Required Characteristic QA.2.3.3 became effective for accreditation purposes on January 1, 1989.

The revised standard and required characteristics concerning the monitoring and evaluation process (QA.3 through QA.3.2.8) became effective for accreditation purposes on July 1, 1989.

The revised required characteristic concerning the monitoring and evaluation of specific services (QA.2.2) becomes effective for accreditation purposes on January 1, 1990.

Notes and Comments:

Plant, Technology, and Safety Management (PL)

Standard

Circle One

- PL.1** There is a safety management program that is designed to provide a physical environment free of hazards and to manage staff activities to reduce the risk of human injury.*

1 2 3 4 5 NA

Required Characteristics

- PL.1.1** The governing body strives to assure a safe environment for patients, personnel, and visitors by requiring and supporting the establishment and maintenance of an effective safety management program.*

1 2 3 4 5 NA

- PL.1.2** A safety officer appointed by the chief executive officer or his designee and qualified by experience and/or education is responsible for the development, implementation, and monitoring of the safety management program.*

1 2 3 4 5 NA

- PL.1.3** The safety management program is based on monitoring and evaluation of organizational experience, applicable law and regulation, and accepted practice and includes*

1 2 3 4 5 NA

PL.1.3.1 policies and procedures for safety in all departments/services;*

1 2 3 4 5 NA

PL.1.3.2 a risk-assessment program that evaluates the impact on patient care and safety of the buildings, grounds, occupants, and internal physical systems;*

1 2 3 4 5 NA

PL.1.3.3 special attention to hazards related to the ages of the patients served; and

1 2 3 4 5 NA

*The asterisked items are key factors in the accreditation decision process. For an explanation of the use of the key factors, see "Using the Manual," page xi.

Circle One

PL.1.3.4 policies and procedures for the timely reporting and resolution of situations that pose an immediate threat to life, health, and/or property.*

1 2 3 4 5 NA

PL.1.3.4.1 The policies and procedures are approved in writing by the chief executive officer and the chief officer of the medical staff.*

1 2 3 4 5 NA

PL.1.4 The safety officer manages an ongoing hospitalwide process to collect and evaluate information about hazards and safety practices that is used to identify safety management issues to be addressed by the safety committee; the information collection and evaluation system includes*

1 2 3 4 5 NA

PL.1.4.1 documented surveys, at least semiannually, of all areas of the facility to identify environmental hazards and unsafe practices;*

1 2 3 4 5 NA

PL.1.4.2 a system for reporting and investigating all incidents that involve patient, personnel, or visitor injury, occupational illness, or property damage; and*

1 2 3 4 5 NA

PL.1.4.3 summaries of actions taken as the result of other hospitalwide monitoring activities, including quality assurance and risk management.*

1 2 3 4 5 NA

PL.1.5 There is a safety committee, appointed by the chief executive officer or his designee, composed of representatives of administration, clinical services, and support services.*

1 2 3 4 5 NA

PL.1.5.1 The safety committee meets at least every other month to analyze identified safety management issues and to develop recommendations for resolving them.*

1 2 3 4 5 NA

PL.1.6 The safety officer works with appropriate staff to implement safety committee recommendations and to monitor the effectiveness of the changes.*

1 2 3 4 5 NA

PL.1.6.1 The results of monitoring are reported to the safety committee.

1 2 3 4 5 NA

PL.1.7 Identified safety management issues and summaries of safety committee activities are communicated at least quarterly to the governing body, chief executive officer, directors of all departments/services, and those responsible for other monitoring activities, including quality assurance and risk management.*

1 2 3 4 5 NA

PL.1.8 All new personnel are oriented to the safety management program, and all personnel participate in continuing safety education and training.*

1 2 3 4 5 NA

PL.1.8.1 The orientation and continuing education and training address general safety management issues, departmental safety plans, special hazards related to assigned duties, safety practices specific to the ages of the patients served, and changes in the safety management program derived from safety committee activities.*

1 2 3 4 5 NA

*The asterisked items are key factors in the accreditation decision process. For an explanation of the use of the key factors, see "Using the Manual," page xi.

Circle One

PL.1.9	The objectives, scope, organization, and effectiveness of the safety management program are evaluated at least annually and revised as necessary.*	1 2 3 4 5 NA
PL.1.10	There is a hazardous materials and wastes program, designed and operated in accordance with applicable law and regulation, to identify and control hazardous materials and wastes; the program includes*	1 2 3 4 5 NA
	PL.1.10.1 policies and procedures for identifying, handling, storing, using, and disposing of hazardous materials from receipt through use and hazardous wastes from generation to final disposal;*	1 2 3 4 5 NA
	PL.1.10.2 training for and, as appropriate, monitoring of personnel who manage and/or regularly come into contact with hazardous materials and/or wastes;*	1 2 3 4 5 NA
	PL.1.10.3 monitoring of compliance with the program's requirements; *and	1 2 3 4 5 NA
	PL.1.10.4 evaluation of the effectiveness of the program, with reports to the safety committee and to those responsible for other appropriate monitoring activities.*	1 2 3 4 5 NA
PL.1.11	There is an emergency preparedness program designed to manage the consequences of natural disasters or other emergencies that disrupt the hospital's ability to provide care and treatment; the program includes*	1 2 3 4 5 NA
	PL.1.11.1 a description of the hospital's role in communitywide emergency preparedness plans;*	1 2 3 4 5 NA
	PL.1.11.2 information about how the hospital plans to implement specific procedures in response to environmental or man-made events;*	1 2 3 4 5 NA
	PL.1.11.3 provisions for the management of space, supplies, communications, and security;*	1 2 3 4 5 NA
	PL.1.11.4 provisions for the management of staff, including distribution and assignment of responsibilities and functions;*	1 2 3 4 5 NA
	PL.1.11.5 provisions for the management of patients, including scheduling of services, control of patient information, and admission, transfer, and discharge;*	1 2 3 4 5 NA
	PL.1.11.6 staff training in their roles during emergencies;* and	1 2 3 4 5 NA
	PL.1.11.7 semiannual implementations of the plan, either in response to an emergency or in a planned drill.*	1 2 3 4 5 NA
	PL.1.11.7.1 The hospital's performance during implementations of the plan is evaluated, documented, and reported to the safety committee through the hospitalwide information collection and evaluation system (see Required Characteristic PL.1.4).*	1 2 3 4 5 NA

*The asterisked items are key factors in the accreditation decision process. For an explanation of the use of the key factors, see "Using the Manual," page xi.

Standard

Circle One

- PL.2** There is a life safety management program designed to protect patients, personnel, visitors, and property from fire and the products of combustion and to provide for the safe use of buildings and grounds.*

1 2 3 4 5 NA

Required Characteristics

NA

- PL.2.1** Each building in which patients are housed overnight or receive treatment is in compliance with the appropriate provisions of the 1988 edition of the *Life Safety Code*® of the National Fire Protection Association (NFPA), or equivalent protection is provided and documented.*†

1 2 3 4 5 NA

PL.2.1.1 A comprehensive Statement of Construction and Fire Protection, submitted to the Joint Commission, describes the structural features of fire protection of the facility.*

1 2 3 4 5 NA

PL.2.1.2 When requirements of the *Life Safety Code*® and these standards or their equivalents are not met, a comprehensive plan of correction is developed.*

1 2 3 4 5 NA

PL.2.1.3 When requirements for fire protection or environment and grounds safety are affected by construction, the hospital institutes and documents interim life safety measures to temporarily compensate for the hazard posed by existing life safety deficiencies.*

1 2 3 4 5 NA

PL.2.1.4 The interim life safety measures are continued and documented so that the level of life safety is not diminished in any occupied area and a safe environment and grounds are maintained throughout construction of and/or alteration to buildings and/or grounds.*

1 2 3 4 5 NA

- PL.2.2** There is an ongoing program designed to assure that the buildings and grounds are suitable to the nature of the services provided and the ages and other characteristics of the patient population served.*

1 2 3 4 5 NA

PL.2.2.1 New construction provides for the safe and convenient use of buildings and grounds by physically disabled individuals.*

1 2 3 4 5 NA

PL.2.2.2 The hospital has specific policies for the maintenance, supervision, and safe use by patients of all grounds and equipment, including special activity areas.*

1 2 3 4 5 NA

PL.2.2.3 Emergency departments/services are readily identifiable and easily accessible.*

1 2 3 4 5 NA

PL.2.2.3.1 There are policies that address vehicular access to the emergency care areas.*

1 2 3 4 5 NA

*The asterisked items are key factors in the accreditation decision process. For an explanation of the use of the key factors, see "Using the Manual," page xi.

†The Joint Commission references the 1988 edition of the *Life Safety Code*® (NFPA 101®) of the National Fire Protection Association. As of January 1, 1989, all Joint Commission-accredited facilities are being surveyed for compliance with the 1988 *Life Safety Code*®. The "code effective date" is January 1, 1989. Buildings for which plans were approved after that date are considered "new construction" for purposes of determining compliance with the 1988 *Life Safety Code*®.

Life Safety Code® and 101® are registered trademarks of the National Fire Protection Association, Inc., Quincy, Massachusetts.

		Circle One
	PL.2.2.4 Compliance with the requirements of the program is documented.*	1 2 3 4 5 NA
PL.2.3	There is an ongoing program designed to establish and maintain fire safety.*	1 2 3 4 5 NA
	PL.2.3.1 The program is established through the following:	
	PL.2.3.1.1 Procedures to identify and maintain all applicable required features of fire protection to <i>Life Safety Code</i> ® standards.*	1 2 3 4 5 NA
	PL.2.3.1.2 Procedures for inspecting, testing, and maintaining fire-alarm and fire-detection systems, including quarterly testing of all circuits and annual preventive maintenance of all components.*	1 2 3 4 5 NA
	PL.2.3.1.3 Procedures for inspecting and testing all automatic fire-extinguishing systems annually.*	1 2 3 4 5 NA
	PL.2.3.1.4 Procedures for the management of portable fire extinguishers, including guidelines for their identification, placement, and use; a quarterly inspection program; and a regular maintenance program.*	1 2 3 4 5 NA
	PL.2.3.1.5 Procedures to review proposed acquisitions of bedding, window draperies and other curtains, furnishings, decorations, wastebaskets, and other equipment to identify issues related to fire safety.*	1 2 3 4 5 NA
	PL.2.3.2 The program is maintained through the following:	
	PL.2.3.2.1 As appropriate to occupancy classification, a fire-alarm or fire-detection system that upon activation minimizes smoke transmission through control of designated fans and/or dampers in air-handling and smoke-management systems.*	1 2 3 4 5 NA
	PL.2.3.2.2 A fire plan that addresses appropriate staff response to a fire emergency and appropriate education and training for all personnel in all elements of the fire plan.*	1 2 3 4 5 NA
	PL.2.3.2.3 For all personnel on all shifts in all patient care buildings, quarterly conducting and evaluation of fire drills that test staff knowledge of the use and function of the fire-alarm systems, transmission of alarms, containment of smoke and fire, transfer to areas of refuge, fire extinguishment, assignment of specific duties, and preparation for building evacuation.*	1 2 3 4 5 NA
	PL.2.3.2.4 A smoking policy in accordance with Required Characteristics MA.1.4.20 and MA.1.4.20.1.	1 2 3 4 5 NA
	PL.2.3.3 Compliance with the requirements of the program is documented.*	1 2 3 4 5 NA
PL.2.4	The documentation of the life safety management program is analyzed, and summaries are reviewed by the safety committee and other appropriate staff.*	1 2 3 4 5 NA

*The asterisked items are key factors in the accreditation decision process. For an explanation of the use of the key factors, see "Using the Manual," page xi.

Circle One

PL.2.4.1 When problems are identified in the life safety management program, actions are taken to resolve them.*

1 2 3 4 5 NA

PL.2.4.1.1 The actions are documented.*

1 2 3 4 5 NA

PL.2.4.1.2 The actions are evaluated for effectiveness.*

1 2 3 4 5 NA

PL.2.4.1.2.1 Once an action is proved effective, the need for continued monitoring of the problem is evaluated.

1 2 3 4 5 NA

PL.2.4.2 As a part of the hospitalwide information collection and evaluation system (see Required Characteristic PL.1.4), appropriate information from the hospital's life safety management program is referred to the safety committee for review, analysis, and, as appropriate, action.*

1 2 3 4 5 NA

Standard

PL.3 There is an equipment management program designed to assess and control the clinical and physical risks of fixed and portable equipment used for the diagnosis, treatment, monitoring, and care of patients and of other fixed and portable electrically powered equipment.*

1 2 3 4 5 NA

Required Characteristics

PL.3.1 Written criteria, which include characteristics of equipment function, clinical application, maintenance requirements, and equipment incident history, are used to identify equipment to be included in the program.*

1 2 3 4 5 NA

PL.3.1.1 Before a piece or type of equipment is used, it is evaluated for inclusion in the program, and the evaluation is documented.*

1 2 3 4 5 NA

PL.3.2 A current, accurate, unique inventory is kept of all equipment included in the program, regardless of the equipment's ownership or purpose.*

1 2 3 4 5 NA

PL.3.2.1 Each piece or type of equipment listed in the inventory has written equipment-testing procedures and user-training programs designed to manage the clinical and physical risks.*

1 2 3 4 5 NA

PL.3.2.1.1 Each piece of equipment is tested prior to initial use and at least annually thereafter; such testing is documented.*

1 2 3 4 5 NA

PL.3.2.1.2 Orientation and at least annual continuing education of individuals who use and/or maintain the equipment are documented.*

1 2 3 4 5 NA

PL.3.3 The equipment management program is used to identify and document equipment failures and user errors that have or may have an adverse effect on patient safety and/or the quality of care.*

1 2 3 4 5 NA

*The asterisked items are key factors in the accreditation decision process. For an explanation of the use of the key factors, see "Using the Manual," page xi.

Circle One

PL.3.3.1 Summaries of equipment failures and user errors and relevant published reports of equipment hazards are reviewed by the safety committee and other appropriate staff to identify equipment performance and/or use problems.*

1 2 3 4 5 NA

PL.3.3.2 When problems are identified, actions are taken to resolve them.*

1 2 3 4 5 NA

PL.3.3.2.1 The actions are documented.*

1 2 3 4 5 NA

PL.3.3.2.2 The actions are evaluated for effectiveness.*

1 2 3 4 5 NA

PL.3.3.2.2.1 Once an action is proved effective, the need for continued monitoring of the problem is evaluated.

1 2 3 4 5 NA

Standard

PL.4 There is a utilities management program designed to assure the operational reliability, assess the special risks, and respond to failures of utility systems that support the patient care environment.*

1 2 3 4 5 NA

Required Characteristics

PL.4.1 Written criteria, which include utilities for life support, infection control, environmental support, and equipment support elements, are used to identify utilities to be included in the program.*

1 2 3 4 5 NA

PL.4.2 There is a reliable, adequate emergency power system to provide electricity to designated areas during interruption of the normal electrical source.*

1 2 3 4 5 NA

PL.4.2.1 As required by occupancy classification, the emergency power system provides electricity to at least the following:

PL.4.2.1.1 Alarm systems;*

1 2 3 4 5 NA

PL.4.2.1.2 Blood, bone, and tissue storage units;*

1 2 3 4 5 NA

PL.4.2.1.3 Obstetric delivery rooms;*

1 2 3 4 5 NA

PL.4.2.1.4 Egress illumination;*

1 2 3 4 5 NA

PL.4.2.1.5 Elevators (at least one);*

1 2 3 4 5 NA

PL.4.2.1.6 Emergency care areas;*

1 2 3 4 5 NA

PL.4.2.1.7 Emergency communication systems;*

1 2 3 4 5 NA

PL.4.2.1.8 Illumination of exit signs;*

1 2 3 4 5 NA

PL.4.2.1.9 Medical air compressors;*

1 2 3 4 5 NA

PL.4.2.1.10 Medical/surgical vacuum systems;*

1 2 3 4 5 NA

PL.4.2.1.11 Newborn nurseries;*

1 2 3 4 5 NA

PL.4.2.1.12 Operating rooms;*

1 2 3 4 5 NA

*The asterisked items are key factors in the accreditation decision process. For an explanation of the use of the key factors, see "Using the Manual," page xi.

		Circle One
	PL.4.2.1.13 Postoperative recovery rooms; *and	1 2 3 4 5 NA
	PL.4.2.1.14 Special care units.*	1 2 3 4 5 NA
PL.4.3	A current, accurate, unique inventory is kept of all equipment for utilities systems included in the program.*	1 2 3 4 5 NA
PL.4.4	Utility system operational plans are written to help assure reliability, control risks, reduce failures, and train users and operators of the systems.*	1 2 3 4 5 NA
	PL.4.4.1 The hospital develops procedures and establishes intervals for the testing and maintenance of equipment for utilities systems included in the program.*	1 2 3 4 5 NA
	PL.4.4.2 Tests and inspections that support operational reliability and manage risks are documented.*	1 2 3 4 5 NA
	PL.4.4.3 Orientation and at least annual continuing education for individuals who use and/or maintain utility systems are documented.*	1 2 3 4 5 NA
PL.4.5	There is a current, complete set of documents that indicates the distribution of and controls for partial or complete shutdown of each utility system.*	1 2 3 4 5 NA
	PL.4.5.1 Where provided, emergency shutoff controls are labeled.*	1 2 3 4 5 NA
PL.4.6	The utilities management program is used to identify and document utility problems, failures, and user errors that are or may be a threat to the patient care environment.*	1 2 3 4 5 NA
	PL.4.6.1 Summaries of utility problems, failures, and relevant published information of utility system hazards are reviewed by the safety committee and other appropriate staff to evaluate utility system performance.*	1 2 3 4 5 NA
	PL.4.6.2 When problems are identified, actions are taken to resolve them.*	1 2 3 4 5 NA
	PL.4.6.2.1 The actions are documented.*	1 2 3 4 5 NA
	PL.4.6.2.2 The actions are evaluated for effectiveness.*	1 2 3 4 5 NA
	PL.4.6.2.2.1 Once an action is proven effective, the need for continued monitoring of the problem is evaluated.	1 2 3 4 5 NA

*The asterisked items are key factors in the accreditation decision process. For an explanation of the use of the key factors, see "Using the Manual," page xi.

The "Plant, Technology, and Safety Management" chapter became effective for accreditation purposes on January 1, 1989.

The added required characteristics concerning the safety management program (PL.1.3.3) become effective for accreditation purposes on January 1, 1990.

The revised required characteristic concerning the orientation and continuing safety education and training program (PL.1.8.1) becomes effective for accreditation purposes on January 1, 1990.

The added required characteristic concerning the hospital's smoking policy (PL.2.3.2.4) becomes effective for accreditation purposes on January 1, 1990.

Infection Control (IC)

Standard	Circle One
IC.1 There is an effective hospitalwide program for the surveillance, prevention, and control of infection.*	1 2 3 4 5 NA
Required Characteristics	
IC.1.1 All patient care and patient care support departments/services are included in the program.*	1 2 3 4 5 NA
IC.1.2 There are written policies and procedures that describe	
IC.1.2.1 the role and scope of participation of each department/ service in infection prevention and control activities;* and	1 2 3 4 5 NA
IC.1.2.2 the role and scope of participation of employee health activities in the program.*	1 2 3 4 5 NA
IC.1.3 There are written policies and procedures that describe the types of surveillance carried out to monitor the rates of nosocomial infections, the systems used to collect and analyze data, and the activities to prevent and control infection.*	1 2 3 4 5 NA
IC.1.3.1 There is ongoing review and analysis of nosocomial infection data, risk factors, and as needed, special studies that relate to infection prevention and control.*	1 2 3 4 5 NA
IC.1.3.1.1 Laboratory support, particularly microbiological and serological, is provided.*	1 2 3 4 5 NA
IC.1.3.1.2 Nosocomial infection data, using, as appropriate, rates stratified by infection risk or focused infection studies, are collected on an ongoing basis for the following purposes:*	1 2 3 4 5 NA
IC.1.3.1.2.1 To monitor the effects of intervention strategies on the infection rates;*	1 2 3 4 5 NA

*The asterisked items are key factors in the accreditation decision process. For an explanation of the use of the key factors, see "Using the Manual," page xi.

Circle One

IC.1.3.1.2.2 To provide feedback to selected groups of physicians, nurses, and support staff about the nosocomial infection risk of their patients.*	1 2 3 4 5 NA
IC.1.3.2 Activities are conducted to prevent and control infections in patients and personnel.*	1 2 3 4 5 NA
IC.1.3.2.1 Written policies define the indications for specific precautions to prevent transmission of infection, including*	1 2 3 4 5 NA
IC.1.3.2.1.1 adequate infection control devices and supplies are available in patient care areas;* and	1 2 3 4 5 NA
IC.1.3.2.1.2 filled infectious waste containers are disposed of in a timely manner in accordance with the hospital's hazardous materials and waste program.*	1 2 3 4 5 NA
IC.1.3.2.2 Persons qualified in infection surveillance, prevention, and control provide consultation regarding the purchase of all equipment and supplies used for sterilization, disinfection, and decontamination purposes; and	1 2 3 4 5 NA
IC.1.3.2.3 Cleaning procedures, agents, and schedules in use throughout the hospital are periodically reviewed.*	1 2 3 4 5 NA
IC.1.3.2.3.1 Persons qualified in infection surveillance, prevention, and control provide consultation regarding any major change in cleaning products or techniques.	1 2 3 4 5 NA

Standard

IC.2 A multidisciplinary committee oversees the program for surveillance, prevention, and control of infection.*	1 2 3 4 5 NA
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Required Characteristics

IC.2.1 Committee membership includes representatives from at least the medical staff, nursing, administration, and the person or persons directly responsible for management of the infection surveillance, prevention, and control program.*	1 2 3 4 5 NA
IC.2.1.1 Representation from housekeeping, central services, laundry, the dietetic department/service, the engineering and maintenance department/service, pharmacy, and the operating suite is recommended on at least a consultative basis.	1 2 3 4 5 NA
IC.2.1.2 The infection control committee includes an individual whose credentials document knowledge of, and special interest or experience in, infection control.	1 2 3 4 5 NA
IC.2.1.2.1 It is recommended, but not required, that the committee chairman be a physician.	
IC.2.1.3 The infection control committee meets not less than quarterly.*	1 2 3 4 5 NA

*The asterisked items are key factors in the accreditation decision process. For an explanation of the use of the key factors, see "Using the Manual," page xi.

		Circle One
IC.2.2	The committee approves the type and scope of surveillance activities, which include at least the following:*	1 2 3 4 5 NA
	IC.2.2.1 review of designated microbiological reports;*	1 2 3 4 5 NA
	IC.2.2.2 review of patient infections, as appropriate, to determine whether an infection is nosocomial, using definitions and criteria approved by the committee;*	1 2 3 4 5 NA
	IC.2.2.2.1 review focuses on those infections that present the potential for prevention or intervention to reduce the risk of future occurrence.*	1 2 3 4 5 NA
	IC.2.2.2.2 review is directed to surveillance data, when available, looking particularly for	1 2 3 4 5 NA
	IC.2.2.2.2.1 unusual epidemics;	1 2 3 4 5 NA
	IC.2.2.2.2.2 clusters of infections;	1 2 3 4 5 NA
	IC.2.2.2.2.3 infections due to unusual pathogens; and	1 2 3 4 5 NA
	IC.2.2.2.2.4 any occurrence of nosocomial infection that exceeds the usual baseline levels.	1 2 3 4 5 NA
	IC.2.2.3 prevalence and incidence studies, if appropriate; and*	1 2 3 4 5 NA
	IC.2.2.4 routine or special collection of other data, as approved by the committee.*	1 2 3 4 5 NA
	IC.2.2.4.1 Sampling of personnel or the environment for infective agents is done only at the direction of the committee, or its designee, and only in accordance with applicable law or regulation.	1 2 3 4 5 NA
IC.2.3	The committee approves actions to prevent or control infection, based on an evaluation of the surveillance reports of infections and of the infection potential among patients and hospital personnel.*	1 2 3 4 5 NA
	IC.2.3.1 Conclusions, recommendations, and actions are documented in the minutes of the committee.*	1 2 3 4 5 NA
	IC.2.3.2 The minutes are forwarded to the medical staff (through the executive committee), the chief executive officer, the nursing administrator, and the person(s) responsible for the hospitalwide quality assurance activity.*	1 2 3 4 5 NA
	IC.2.3.2.1 The responsibility for taking action on the recommendations documented in the minutes is assigned and defined in writing.*	1 2 3 4 5 NA
IC.2.4	The committee reviews and approves, at least every two years, all policies and procedures related to the infection surveillance, prevention, and control program and to infection surveillance, prevention, and control activities in all departments/services.*	1 2 3 4 5 NA
	IC.2.4.1 Reviews and approvals are documented in the minutes of the committee.	1 2 3 4 5 NA

*The asterisked items are key factors in the accreditation decision process. For an explanation of the use of the key factors, see "Using the Manual," page xi.

Circle One

- IC.2.5** The authority of the committee, or its designee, to institute any surveillance, prevention, and control measures or studies when there is reason to believe that any patient or personnel may be in danger, is defined in writing and approved by the administration and medical staff.* 1 2 3 4 5 NA
- IC.2.5.1 The statement of authority is reviewed and authenticated every two years by the administration and the medical staff.* 1 2 3 4 5 NA

Standard

- IC.3** Responsibility for the management of infection surveillance, prevention, and control is assigned to a qualified person(s).* 1 2 3 4 5 NA

Required Characteristics

- IC.3.1** There is documented evidence that the person(s) has education, training, or supervised experience related to infection surveillance, prevention, and control. 1 2 3 4 5 NA
- IC.3.2** The amount of time the person(s) spends in infection surveillance, prevention, and control activities is related to the needs of the hospital, as defined by the committee responsible for overseeing the infection surveillance, prevention, and control program.* 1 2 3 4 5 NA

Standard

- IC.4** There are written policies and procedures for infection surveillance, prevention, and control for all patient care departments/services.* 1 2 3 4 5 NA

Required Characteristics

- IC.4.1** The written policies and procedures are made known to personnel doing patient care procedures that are associated with the potential for infection. 1 2 3 4 5 NA
- IC.4.1.1 All personnel are competent to participate in infection monitoring, prevention, and control activities and are provided with any necessary orientation, on-the-job and in-service training, and continuing education.* 1 2 3 4 5 NA
- IC.4.1.1.1 All educational activity is documented.* 1 2 3 4 5 NA

*The asterisked items are key factors in the accreditation decision process. For an explanation of the use of the key factors, see "Using the Manual," page xi.

Standard	Circle One
IC.5 Patient care support departments/services, such as central services, housekeeping services, and linen and laundry services, are available to assist in the prevention and control of infections and are provided with adequate direction, staffing, and facilities to perform all required infection surveillance, prevention, and control functions.*	1 2 3 4 5 NA
Required Characteristics	
IC.5.1 When the hospital conducts decontamination and sterilization activities, there are specific written policies and procedures for these activities.*	1 2 3 4 5 NA
IC.5.1.1 The performance of all sterilizing equipment throughout the hospital is monitored.*	1 2 3 4 5 NA
IC.5.1.2 There are written policies addressing the shelf life of all stored sterile items.*	1 2 3 4 5 NA
IC.5.1.3 There are written policies and procedures addressing the reuse of disposable items.*	1 2 3 4 5 NA
IC.5.1.3.1 These policies and procedures address the reprocessing of disposable items to be reused.*	1 2 3 4 5 NA
IC.5.2 Soiled and contaminated supplies are separated from those that are clean and sterile either by facility design or by the management of work flow, in accordance with written policies and procedures.	1 2 3 4 5 NA
IC.5.3 The laundry service provides, either directly or in accordance with a written agreement with an outside source, an adequate supply of clean linen.	1 2 3 4 5 NA
IC.5.3.1 Clean linen is delivered to the user in such a way as to minimize microbial contamination from surface contact or airborne deposition.	1 2 3 4 5 NA
IC.5.3.2 Soiled linen is collected in such a manner as to minimize microbial dissemination into the environment.	1 2 3 4 5 NA

*The asterisked items are key factors in the accreditation decision process. For an explanation of the use of the key factors, see "Using the Manual," page xi.

The "Infection Control" chapter becomes effective for accreditation purposes on January 1, 1990.

Notes and Comments:

Using the Manual

The *Accreditation Manual for Hospitals* is designed for use in hospital self-assessment and is the basis for the survey report forms that Joint Commission surveyors use to record their on-site survey findings. The accreditation report sent to the hospital directly quotes standards, permitting hospital personnel to consult specific provisions of this *Manual* in carrying out postsurvey recommendations.

All chapters of this *Manual* are in outline format to enhance readability, to clarify the intent of each standard and required characteristic, and to facilitate use of this *Manual* as a self-assessment guide. The numbering system for standards and required characteristics also provides ready reference to standards. Each standard and required characteristic is given a two-letter code standing for the title of the chapter in which it appears and then is numbered according to order of appearance within the chapter.

The standards and required characteristics that are most important to the accreditation decision process, referred to as key factors, are identified with an asterisk throughout this *Manual*. Although all standards and required characteristics have important implications for the delivery of high-quality health care, key factors are central to the accreditation decision. The asterisks are intended to assist the hospital in assessing their compliance with the key factors.

The rating scale, which is used by surveyors to assess and report levels of compliance with standards, contains six rankings—the numbers 1 through 5 and NA (not applicable). This scale may also be used by hospital staff in self-assessment. An explanation of the scale follows:

- 1 Substantial compliance**, indicates that the hospital consistently meets all major provisions of the standard or required characteristic.
 - 2 Significant compliance**, indicates that the hospital meets most provisions of the standard or required characteristic.
 - 3 Partial compliance**, indicates that the hospital meets some provisions of the standard or required characteristic.
 - 4 Minimal compliance**, indicates that the hospital meets few provisions of the standard or required characteristic.
 - 5 Noncompliance**, indicates that the hospital fails to meet the provisions of the standard or required characteristic.
- NA Not applicable**, indicates that the standard or required characteristic does not apply to the hospital.

Space is provided at the end of each chapter for hospital staff conducting a self-assessment to record comments and note actions to be taken to bring the hospital into compliance with specific standards and required characteristics.

As part of their self-evaluation activities, hospital staff members are strongly encouraged to read *Joint Commission Perspectives*, the official bimonthly newsletter. All changes in standards and in survey policies and procedures are reported in the newsletter.

MAJORITY MEMBERS

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H. MARTIN LANCASTER, NORTH CAROLINA
ED PASTOR, ARIZONA

102d Congress

United States House of Representatives
Committee on Small Business
Subcommittee on Regulation,
Business Opportunities, and Energy
B-363 Rayburn House Office Building
Washington, DC 20515-6318

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202-225-7787

GRAYDON J. FORMER
SUBCOMMITTEE COUNSEL

JENIFER LOOM
MINORITY SUBCOMMITTEE PROFESSIONAL
STAFF MEMBER
202-225-2555

February 10, 1992

Dr. Thomas Arrowsmith-Lowe, D.D.S.
Deputy Director
Office of Health Affairs and Aids Coordination
The Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857

Dear Dr. Arrowsmith-Lowe:

Thank you for your cooperation with the subcommittee at its February 7, 1992, hearing on the problems posed to healthcare workers from needle stick injuries.

As you are aware, during the hearing questions were raised about the safety and efficacy of several sharps and needles produced by a number of manufacturers. Specifically, several of the witnesses contended that a number of prominent medical equipment manufacturers are continuing to produce and market a number of unnecessary, if not unsafe, needles and sharps. In particular, the testimony of Dr. Janine Jagger raised troubling questions about the products of the Terumo, Sterling and Wyeth companies when she stated that these manufacturers "have categorically ignored the safety concerns raised by their products."

Clearly, if these and other manufacturers are producing and marketing products that are now obsolete and actually contributing to dangerous accidental needlestick and other sharps injuries, then action would appear to be necessary to move these un-safe products out of the marketplace.

At the hearing, I requested that the Food and Drug Administration (FDA), working with the Centers for Disease Control (CDC), evaluate Dr. Jagger's charges and move quickly to bring whatever powers the FDA has to bare to eliminate these unnecessary and potentially dangerous products from the market place.

Dr. Arrowsmith-Lowe
Page Two.

I request that the FDA, with the aid of the CDC, answer the following questions for the record of the subcommittee hearing:

1. Are there needles and sharps currently in the marketplace that are unnecessary and potentially unsafe?
2. What are these products and who manufactured them?
3. Have these devices been approved by the FDA?
4. Can the FDA remove previously approved devices from the marketplace if it is established that these devices are either obsolete or now pose a danger to the public?
5. Has the FDA taken any steps to remove potentially unsafe needles and sharps from the marketplace?

Please respond to this request within 30 working days.

Should you have any questions regarding this request, please don't hesitate to contact Graydon Forrer or Steve Jennings of the subcommittee staff at (202)225-7797.

Your cooperation and assistance in this matter are appreciated.

Sincerely,


RON WYDEN
Chairman

cc: Dr. David M. Bell, M.D.
The Center for Disease Control
RW/gjf



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

The Honorable Ron Wyden
Chairman, Subcommittee on Regulation,
Business Opportunities, and Energy
Committee on Small Business
House of Representatives
Washington, D.C. 20515

APR 23 1992

Dear Mr. Chairman:

This is in response to your February 10, 1992, letter to Dr. Thomas Arrowsmith-Lowe, submitting additional questions for the record of the February 7, 1992, hearing on the problems posed to health care workers from needlestick injuries.

As was discussed in detail at the hearing, health care workers may face a risk of infection with a bloodborne pathogen as a result of exposures which occur in the health care setting. Percutaneous exposures, where the skin is penetrated by a sharp object, such as a needle, contaminated with the blood of another person, pose the greatest risk of bloodborne infection. Bloodborne infections transmitted in the health care setting include hepatitis B virus (HBV), hepatitis C virus (HCV), human immunodeficiency virus (HIV), and others. Many of the sharps (needles, syringes, scalpels, etc.) used in health care are necessary to inject medications, conduct surgery, etc. With those products, modifications in the design of the device to reduce the chance of inadvertent penetration of the skin may decrease the associated risks. As was stated in the hearing, some sharps may not be necessary. For those products, elimination of the sharp may be preferable to merely providing protection from the sharp.

Most sharps products are legally marketed as pre-amendments devices, which means that they were marketed prior to the enactment date (May 28, 1976) of the Medical Device Amendments to the Federal Food, Drug and Cosmetic Act. Section 510(k) of the Act contains a premarket notification requirement. It applies to all post-enactment devices (i.e., devices introduced into commercial distribution after May 28, 1976). With some limited exceptions, premarket notification is required of all manufacturers who, after that date, introduce a device into the market for the first time, or introduce a device that incorporates a significant change or modification in design, components, method of manufacture or intended use. Manufacturers are required to submit a premarket notification to the Food and Drug Administration (FDA) in order to establish substantial equivalence, in terms of safety and effectiveness,

Page 2 - The Honorable Ron Wyden

to a predicate device already on the market in the U.S. prior to May 28, 1976, or to a predicate device marketed after that date, which has been determined to be substantially equivalent.

Substantial equivalence means, with respect to a device being compared to a predicate device, that the device has the same intended use as the predicate device and that FDA has found that the device: 1) has the same technological characteristics as the predicate device; or, 2) has different technological characteristics but the information submitted, including clinical data if necessary, demonstrates that the device is as safe and effective as a legally marketed device, and does not raise questions of safety and efficacy different from the predicate device.

FDA has cleared for market, through the 510(k) process, over 50 products with the intended use of reducing the risk of needlesticks. These products have been developed by both large companies and by individual entrepreneurs. Some of these products are self-activating while others require action on the part of the user. As was pointed out by one of the witnesses at the hearing, the users may not always activate the safety mechanism.

Responding directly to your questions, we are not aware of any needles and sharps currently on the market that have not gone through the 510(k) process, nor have we taken action against any such products because they were unsafe. The very nature of these products makes them potential hazards if used in an inappropriate manner. FDA does have the authority to remove products from the market that are in violation of the medical devices law.

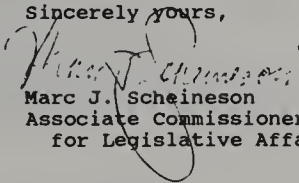
Although we do not have a list of unnecessary and unsafe products, we are going to provide information directly to health care workers on the high-risk problem with sharps and on ways to decrease that risk. We will do that immediately through the issuance of a Safety Alert, which will alert health care workers to the risk from a product that may account for the greatest risk of needlestick injury, the use of a needle as an IV connector. As well as alerting users to this risk, we will provide them with the characteristics of products that can prevent or reduce that risk. Also, we are using the alert to tell users to report to FDA problems with products that can cause needlesticks. Dr. Janine Jagger from the University of Virginia, who proposed this idea, is working directly with us in developing the alert. Along with Dr. Jagger, Ms. Linda Chiarello from the New York State Department of Health and Dr. David Bell from the Centers for Disease Control (CDC) are working with us on the alert.

Page 3 - The Honorable Ron Wyden

As you know, we are planning a conference on the prevention of bloodborne infections for August 17-19, 1992. The objective of this conference is to stimulate the use of new technology as a solution to this problem. The conference will not only showcase state-of-the-art technology, but it will also establish the necessary framework for development, evaluation, and use of even more advanced technological solutions to the needlestick problem.

Let me take this opportunity to invite you or Representative Meyers to speak at this conference. I am certain that you or she would be able to provide an important perspective on the problem of risk to health care workers from needlestick injuries, and add to our discussion of potential solutions. Enclosed is a copy of the preliminary program. The conference agenda is being developed by a committee composed of individuals from CDC, FDA, and the Occupational Safety and Health Administration and chaired by Dr. Murray Cohen of CDC. Dr. Arrowsmith-Lowe may be contacted for additional information or to schedule participation.

Sincerely yours,


Marc J. Scheineson
Associate Commissioner
for Legislative Affairs

Enclosure

cc: The Honorable Jan Meyers
Ranking Minority Member

Preliminary Program

FRONTLINE HEALTHCARE WORKERS:

A NATIONAL
CONFERENCE ON
PREVENTION OF
DEVICE-MEDIATED
BLOODBORNE
INFECTIONS

Washington, D.C.
August 17-19, 1992

Sponsored by:

U.S. DEPARTMENT OF HEALTH
AND HUMAN SERVICES
Public Health Service



Centers for Disease Control



Food & Drug Administration

U.S. DEPARTMENT OF LABOR



Occupational Safety & Health
Administration

FRONTLINE HEALTHCARE WORKERS:

A National Conference on Prevention of Device-Mediated Bloodborne Infections

The Centers for Disease Control (CDC), the Food and Drug Administration (FDA), and the Occupational Safety and Health Administration (OSHA) are sponsoring *Frontline Healthcare Workers: A National Conference on Prevention of Device-Mediated Bloodborne Infections* at the Hyatt Regency Washington on Capitol Hill, Washington, D.C., August 17-19, 1992.

This three-day conference will:

- focus attention on sharps injuries and performance safety of medical devices,
- bring together device manufacturers and users/purchasers to facilitate understanding of needs and interventions pertaining to device-mediated infections, and
- facilitate private sector initiatives for technology advancement, including the development of infection prevention devices and strategies.

CONFERENCE COMMITTEE

Chair

Murray L. Cohen, Ph.D., M.P.H., C.I.H.
Centers for Disease Control

Conference Committee

Centers for Disease Control

Murray L. Cohen, Ph.D., M.P.H., C.I.H.
Lamar Furr
Linda Martin, Ph.D.
Jonathan Richmond, Ph.D.

Food and Drug Administration

J. Thomas Arrowsmith-Lowe, D.D.S., M.P.H.
Alfred Bracey
Tracy Summers
Tim Ulatowski

Occupational Safety and Health Administration

Susan Harwood, Ph.D.
Kevin Landkrohn
Elise Yiasemides, R.N., M.S.Ed., C.O.H.N.

GENERAL INFORMATION

REGISTRATION

Registration is required of all participants. The pre-registration deadline is July 15, 1992. Early enrollment is strongly advised; registration will be limited. To pre-register, please complete the enclosed Conference and Workshop Registration Form and forward with payment to:

FRONTLINE HEALTHCARE WORKERS:
*A National Conference on Prevention of
 Device-Mediated Bloodborne Infections*
 PACE Enterprises, Inc.
 ATTN: Laura Timperio
 17 Executive Park Drive, Suite 200
 Atlanta, GA 30329
 Telephone: (404) 633-8610
 FAX: (404) 633-8745

Registration Fee

The registration fee is \$150. This fee includes both lunch and the evening banquet on Monday, August 17, for those who pre-register with full payment by July 15. Banquet tickets for spouses/guests may be obtained by including an additional \$45 with the registration fee. Confirmation will be sent upon receipt of the Registration Form and payment.

Payment

Full payment (check or money order only) must accompany the Registration Form. **Please make your check or money order payable to: RNI/Frontline Healthcare Workers Conference.** Mail your payment with the Registration Form to the above address.

HOTEL ACCOMMODATIONS

A block of rooms has been reserved at the Hyatt Regency Washington on Capitol

Hill, 400 New Jersey Avenue, N.W., Washington, D.C. 20001. Rates for conference attendees who confirm their reservation before July 15 are: Single - \$97; Double - \$122. (These rates are subject to change according to the prevailing 1992 federal government per diem rates.)

Please contact the hotel directly at (202) 737-1234 in order to make your reservation —be sure to identify yourself as a conference attendee. YOU ARE RESPONSIBLE FOR ARRANGING YOUR OWN HOTEL ACCOMMODATIONS.

WORKSHOPS

Concurrent workshops will be offered on Tuesday, August 18. Each workshop will be led by a facilitator to provide a focused discussion of the subject. **Attendees must register in advance for workshops, as space is limited.** Please indicate your preference on the Workshop Registration Form.

ACCREDITATION - CME, CEU, CIH/CMP

Applications for continuing education credits are under review.

POSTERS

Poster presentations, approved by the Conference Committee from submitted abstracts, will be displayed on Monday and Tuesday. An author must be present in order to facilitate the exchange of information.

ADDITIONAL INFORMATION

For additional information about the conference, please contact Ms. Laura Timperio, PACE Enterprises, Inc., 17 Executive Park Drive, Suite 200, Atlanta, GA 30329. Telephone: (404) 633-8610, or Fax: (404) 633-8745.

CALL FOR ABSTRACTS

Abstracts received by April 1, on the following topics, will be considered:

- Medical device-related infection control issues in healthcare facilities and home settings
- Studies on the safety and effectiveness of medical devices intended to prevent bloodborne disease transmission
- Innovations in device technology to prevent transmission of bloodborne pathogens
- Criteria for user evaluation and selection of devices
- Epidemiology and surveillance of device-mediated bloodborne infections
- Legally marketed medical devices intended to minimize the potential for transmission of bloodborne pathogens to healthcare workers

Scientific soundness of the study and potential significance of the information to the objectives of the conference will be the primary requirements for acceptance of the abstract by the Conference Committee.

ABSTRACTS MAY PRESENT INFORMATION THAT HAS BEEN PUBLISHED OR PRESENTED AT ANOTHER NATIONAL OR INTERNATIONAL MEETING. Persons who submit abstracts should consider them official communications of the conference. If an abstract is accepted, the author is expected to register, attend the conference, and present the poster in person.

All presentations will be in poster session. The poster sessions will be arranged so that posters of a similar topic are all presented at the same time and location. By submitting an abstract, the author agrees to be present as scheduled.

Posters are invited that present legally marketed medical devices intended to minimize the potential for transmission of bloodborne pathogens to healthcare workers. Such devices could include, for example, sharps disposal units, antistick needles, needleless connections, and barrier devices. No distribution of samples will be permitted. However, presenters may provide printed handouts concerning the devices and collect information from prospective customers.

SUBJECT CATEGORIES FOR ABSTRACT SUBMISSION

For purposes of review and arrangement, abstracts will be divided into subject categories. List the letter of the category that most appropriately describes the content of the poster, and enter the letter of that category on Abstract Form I or II, as appropriate.

A. Medical Device-Related Infection Control Issues in Healthcare Facilities and Home Settings - Use Abstract Form I

Abstracts presenting studies and educational information on medical device-related infection control issues in healthcare facilities (hospital, clinic, professional office, etc.) and home settings related to device-mediated bloodborne disease transmission will be considered. Studies and information must be consistent with established guidelines and regulations. Anecdotal information will not be considered.

B. Studies on the Safety and Effectiveness of Medical Devices Intended to Prevent Bloodborne Disease Transmission - Use Abstract Form I

In vitro and in vivo studies on the safety and effectiveness of medical devices (either marketed devices or devices pending commercial availability) intended to prevent bloodborne disease transmission will be considered. The studies must be properly controlled when possible, and contain sufficient sample size, duration, and followup. Abstracts on devices that are not yet commercially available may be accepted, but no handouts will be permitted at the meeting, nor will the authors be permitted to take or accept any information from prospective customers.

C. Innovations in Device Technology to Prevent Transmission of Bloodborne Pathogens - Use Abstract Form I

One objective of the conference is stimulation of technology transfer; i.e., bringing together manufacturers, users, and others to foster development of needed devices. Basic research and development in new technologies that may have a future impact on

bloodborne disease transmission is underway. A wealth of relevant new concepts and ideas is being generated by entrepreneurs, inventors, users and others. Abstracts on these activities and concepts will be considered. Abstracts on devices that are not yet commercially available may be accepted but no handouts will be permitted at the meeting, nor will the authors be permitted to take or accept any information from prospective customers.

D. Criteria for User Evaluation and Selection of Devices - Use Abstract Form I

Individuals who purchase devices intended to prevent bloodborne disease transmission are interested in ways to evaluate and compare features and performance. These methods may include both subjective and objective criteria.

E. Epidemiology and Surveillance of Device-Mediated Bloodborne Infections - Use Abstract Form I

Posters will be considered on the epidemiology and surveillance of device-mediated bloodborne infections from the perspective of healthcare workers. Included as part of this topic are the issues of incidence of bloodborne disease transmission, demographics, and device types associated with transmission. Posters on this topic will serve to stimulate further development of devices and improvement in infection control procedures.

F. Legally Marketed Medical Devices Intended to Minimize the Potential for Transmission of Bloodborne Pathogens - Use Abstract Form II

Posters are invited that present **legally marketed** medical devices intended to minimize the potential for transmission of bloodborne pathogens to healthcare workers. Such devices could include, for example, sharps disposal units, antistick needles, needleless connections, and barrier devices. No distribution of samples will be permitted. However, presenters may provide printed handouts concerning the devices and collect information from prospective customers.

PRELIMINARY PROGRAM

Sunday, August 16, 1992

1:00 - 6:00 Registration

Monday, August 17, 1992

8:00 - 5:00 Registration and Poster Setup

10:00 Welcoming Remarks and Conference Charge

Session I: Plenary - Agency Background Presentations

10:30 - 12:00 CDC Disease and Injury Prevention Responsibilities
FDA Device Regulatory Responsibilities
OSHA Regulatory Responsibilities

... Lunch ...

Session II: Keynote Addresses

1:30 - 3:30 Dr. Janine Jagger, University of Virginia, Charlottesville: "Caring for Healthcare Workers: Injury Hazards With Today's Medical Devices"

Dr. Norman Estrin, Estrin Consulting Group, Potomac, Maryland:
"Market Factors that Affect Changes and Introduction of New Technology"

... Coffee Break ...

Session III: Risk Reality in the Healthcare Setting

4:00 - 5:00 Healthcare Worker Panel

... Social Program ...

7:00 Banquet with Guest Speaker

Tuesday, August 18, 1992

... Continental Breakfast ...

Session IV: Concurrent Workshops

8:00 - 8:30 Charge to Workshop Participants

- 8:30 - 10:15
- A. "Breakouts" on specific work settings
 - Clinical Laboratories
 - Home Health Care
 - Surgery
 - B. FDA/Division of Small Manufacturers Assistance (DSMA) Training Seminar: "From Drawing Board to Consumer." A workshop on medical device development, testing, and regulatory requirements.
 - C. OSHA Training Seminar: "The Bloodborne Pathogens Standard." Discussion of the contents of OSHA's bloodborne pathogens standard and Q & A's with OSHA experts.

... Coffee Break ...

- 10:45 - 12:30
- A. "Breakouts" on specific work settings
 - Dental
 - Inpatient Care
 - B. (Repeat) FDA/Division of Small Manufacturers Assistance (DSMA) Training Seminar: "From Drawing Board to Consumer." A workshop on medical device development, testing, and regulatory requirements.
 - C. (Repeat) OSHA Training Seminar: "The Bloodborne Pathogens Standard." Discussion of the contents of OSHA's bloodborne pathogens standard and Q & A's with OSHA experts.

... Lunch ...

Tuesday (continued)

Session IV: Concurrent Workshops (Continued)

- 1:45 - 3:30
- A. "Breakouts" on specific work settings
 - Emergency Medical Services
 - Outpatient Care
 - B. (Repeat) FDA/Division of Small Manufacturers Assistance (DSMA) Training Seminar: "From Drawing Board to Consumer." A workshop on medical device development, testing, and regulatory requirements.
 - C. (Repeat) OSHA Training Seminar: "The Bloodborne Pathogens Standard." Discussion of the contents of OSHA's bloodborne pathogens standard and Q & A's with OSHA experts.

Session V: Concurrent Poster Sessions

- 3:30 - 5:30
- A. Medical Device-Related Infection Control Issues in Healthcare Facilities and Home Settings
 - B. Studies on the Safety and Effectiveness of Medical Devices Intended to Prevent Bloodborne Disease Transmission
 - C. Innovations in Device Technology to Prevent Transmission of Bloodborne Pathogens
 - D. Criteria for User Evaluation and Selection of Devices
 - E. Epidemiology and Surveillance of Device-Mediated Bloodborne Infections
 - F. Legally Marketed Medical Devices Intended to Minimize the Potential for Transmission of Bloodborne Pathogens to Healthcare Workers

Wednesday, August 19, 1992

... Continental Breakfast ...

Session VI: Panel Discussion

8:30 - 10:00 Case Studies on Successful Needlestick Prevention Programs

... Coffee Break ...

Session VII: Plenary Forum

10:30 - 12:30 Breakout Session Reports

... Lunch ...

Session VIII: "How-To" Workshop

1:30 - 3:30 Evaluation of Device Performance Safety, Product Selection, and Use

3:30 Adjournment

Instructions for Abstract Form I

(Use for Subject Categories A - E)

Read these instructions carefully before typing the abstract in the space provided on the following abstract form.

1. Authors should submit abstracts on the official Abstract Form I, to be received no later than April 1, 1992. Abstracts should be submitted to:
PACE Enterprises, Inc.
ATTN: Laura Timperio
17 Executive Park Drive, Suite 200
Atlanta, GA 30329
Telephone: (404) 633-8610
2. Use a short and complete TITLE that indicates the content of the abstract. Capitalize the first letter of each word except prepositions and articles.
3. Authors' names should be typed in CAPITAL letters. Place an asterisk (*) after the name of the author presenting the poster. Each author should be listed by institution, city, and state. Omit degrees, titles, and full addresses. All institutional affiliations should follow the last author's name.
4. The abstract should contain the following:
 - a. A concise statement of the problem under investigation or educational topic.
 - b. For studies, the experimental method used.
 - c. The essential results obtained (specific findings must be included) in summary form or a summary of the relevant educational information to be presented.
 - d. For studies, the conclusions (statistical analysis should be used when appropriate). It is not satisfactory to state that results will be discussed.
5. To facilitate notification of receipt and disposition of abstracts, the following items must be enclosed with each abstract:
 - a. Five legible black-on-white photocopies (8-1/2 x 11 inches) must be submitted in addition to the original typed abstract.
 - b. One self-addressed stamped post-card no smaller than 3-1/2 x 5-1/2 inches with the title of the paper and the authors' names.
 - c. One self-addressed stamped envelope. The first notification will be mailed when the abstract is received. The second notification, indicating the abstract's disposition, will be mailed by June 1, 1992.
 - d. One card (3 x 5 inches) giving the complete title of the abstract and the names of all authors listed alphabetically, with the name of the author presenting the poster UNDERLINED.
6. Practice typing the abstract before using the abstract form.
7. Single space all typing. Use a font of 10 to 12 characters per inch. DO NOT leave blank lines between the title and body or between paragraphs.
8. DO NOT ERASE on the abstract form. DO NOT FOLD the abstract form.
9. Full information on the preparation and presentation of the poster will be sent to interested parties and to those whose abstracts have been accepted.
10. The letter designating the abstract subject category should be indicated in the box on Abstract Form I.

Abstract Form I (Subject Categories A - E)
Frontline Healthcare Workers: A National Conference on
Prevention of Device-Mediated Bloodborne Infections

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Sample Abstract

Start → Characterizations of the Physiological Responses to Polysaccharides. D.P. DONOVAN,* A.B. STEVENSON, T.C. WINTERS, and J. A. DOE. FDA, Rockville, Md.
 The physiological responses of polysaccharides were characterized by an immuno-plaque procedure for the purpose of demonstrating the biological

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3. These abstracts must include:

- a. TITLE. Capitalize the first letter of each word except prepositions and articles.
- b. The name and address of the presenter.
- c. A brief description of the devices to be presented (include labeling).

4. Additional requirements: (a) The FDA establishment registration number; and (b) a statement that any device to be presented is legally marketed under the Federal Food, Drug and Cosmetic Act.

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7. Single space all typing. Use a font of 10 to 12 characters per inch. DO NOT leave blank lines between the title and body or between paragraphs.

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Hyatt Regency Washington on Capitol Hill
Washington, D.C., August 17-19, 1992

If additional copies are needed, you may photocopy this registration form. Early registration is advised as space is limited.

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All Participants	\$ 150
Additional Banquet Tickets @ \$45 each	\$ _____
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Full payment (check or money order only) must accompany registration. Please make your check or money order payable to: RNI/Frontline Healthcare Workers Conference. Mail this form, with payment, to:

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Tuesday, August 18

8:30 - 10:15

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- A. Breakout on Clinical Laboratories
- B. Breakout on Home Health Care
- C. Breakout on Surgery
- D. FDA/DSMA Training Seminar: "From Drawing Board to Consumer."
- E. OSHA Training Seminar: "The Bloodborne Pathogens Standard."

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10:45 - 12:30

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- G. Breakout on Inpatient Care
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1:45 - 3:30

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- J. Breakout on Emergency Medical Services
- K. Breakout on Outpatient Care
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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Centers for Disease Control
Atlanta GA 30333

APR 16 1992

The Honorable Ron Wyden
Chairman
Subcommittee on Regulation, Business
Opportunities, and Energy
Committee on Small Business
House of Representatives
Washington, D.C. 20515-6319

Dear Mr. Wyden:

Thank you for your letter to Dr. David Ball requesting that the Centers for Disease Control (CDC) provide follow-up information from the hearing on the problems posed to health-care workers from needlestick injuries.

CDC does not collect data on back injuries in hospital workers. However, in response to your request for documentation "that needlesticks had recently surpassed back injuries as the most serious workers compensation injury in hospitals," CDC staff contacted various states to assess the availability of this information. The Ohio State Workers' Compensation Program was the only state program that could provide this data in a timely manner. Summaries of workers' compensation claims do not contain the degree of detail needed to address the comparison.

Ohio maintains detailed workers' compensation records on the frequency of claims and the number of days of work lost by hospital workers. According to Mr. Cliff Timbrook, Manager, Occupational Health and Safety Research, Ohio Bureau of Workers' Compensation, the number of claims for needle/syringe injuries among hospital workers received for 1988, 1989, and 1990 was 6, 10, and 19, respectively. The number of claims for back injuries among hospital workers received for those years was 880, 888, and 889, respectively. There were no reports of days of work lost due to needle/syringe injuries for 1990 compared with a total of 17,328 lost days for back injuries (average 19.8 lost days). As you can see, these data are limited and insufficient to draw conclusions regarding the issue you raise.

Workers' compensation claims are processed by a variety of individual insurance companies. It is possible that the frequency of claims due to needlesticks may surpass those due to back injuries in the experience of a single company. Also,

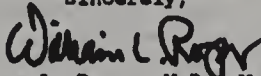
Page 2 - The Honorable Ron Wyden

defining the "seriousness" of a hazard leading to a worker's compensation injury claim may vary depending on which source is consulted. Such definitions may include the frequency of claims received, rate of mortality due to the injury, number of days of hospitalization, number of days of work lost, expense of compensation claims, and amount of pain and suffering caused to a worker and the worker's family.

In the future CDC will publish summary information on reported cases of occupationally acquired HIV infection in CDC's HIV/AIDS Surveillance Report. This report will include the number of reported cases, their occupations, and the types of occupational exposure associated with infection transmission.

I hope this information is helpful to you.

Sincerely,



William L. Roper, M.D., M.P.H.
Director

Response to Chairman Wyden's request for clarification of the number of health-care workers who have acquired HIV infection occupationally:

Infection with HIV leads to a spectrum of illness. Persons in an early stage of infection show no signs or symptoms of disease. Further along the spectrum are persons who have developed some symptoms (e.g., swollen lymph glands) but whose illness does not meet the CDC AIDS case definition. The final stage of HIV infection is the illness meeting the CDC AIDS case definition.

Since 1981, CDC has received reports from state and local health departments of persons who meet the AIDS surveillance case definition. Of the approximately 200,000 persons reported with AIDS, 3 are health-care workers who are known to have acquired their infection from an occupational exposure. These 3 persons did not report transfusion or behavioral risks for HIV infection (e.g., injecting drug use), but had laboratory evidence of a negative test for HIV infection (i.e., tested negative for HIV antibody immediately after the occupational exposure and subsequently tested HIV antibody positive) after documented contact with HIV-infected blood (i.e., an injury with a bloody needle or a blood splash to the eyes, nose, mouth, or skin).

CDC also conducts surveillance of occupationally acquired HIV infection for all health-care workers, regardless of whether the worker has progressed to AIDS. As of December 31, 1991, CDC had received reports of 29 health-care workers in the United States who acquired HIV after a documented occupational exposure; 26 of the HIV-infected workers have not yet developed AIDS and 3 of these health-care workers meet the CDC case definition for AIDS and are included in the AIDS surveillance mentioned above.

In addition, 18 cases of health-care workers with HIV infection (without AIDS) were reported in this surveillance project. these 18 workers did not report other risk factors for HIV infection, but blood specimens were not available to document transmission of infection after specific occupational exposure.

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**Recommendations for
Preventing Transmission of Human
Immunodeficiency Virus and
Hepatitis B Virus to Patients
During Exposure-Prone Invasive
Procedures**

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service
Centers for Disease Control
Atlanta, Georgia 30333



Recommendations for Preventing Transmission of Human Immunodeficiency Virus and Hepatitis B Virus to Patients During Exposure-Prone Invasive Procedures

This document has been developed by the Centers for Disease Control (CDC) to update recommendations for prevention of transmission of human immunodeficiency virus (HIV) and hepatitis B virus (HBV) in the health-care setting. Current data suggest that the risk for such transmission from a health-care worker (HCW) to a patient during an invasive procedure is small; a precise assessment of the risk is not yet available. This document contains recommendations to provide guidance for prevention of HIV and HBV transmission during those invasive procedures that are considered exposure-prone.

INTRODUCTION

Recommendations have been made by the Centers for Disease Control (CDC) for the prevention of transmission of the human immunodeficiency virus (HIV) and the hepatitis B virus (HBV) in health-care settings (1-6). These recommendations emphasize adherence to universal precautions that require that blood and other specified body fluids of all patients be handled as if they contain blood-borne pathogens (1,2).

Previous guidelines contained precautions to be used during invasive procedures (defined in Appendix) and recommendations for the management of HIV- and HBV-infected health-care workers (HCWs) (1). These guidelines did not include specific recommendations on testing HCWs for HIV or HBV infection, and they did not provide guidance on which invasive procedures may represent increased risk to the patient.

The recommendations outlined in this document are based on the following considerations:

- Infected HCWs who adhere to universal precautions and who do not perform invasive procedures pose no risk for transmitting HIV or HBV to patients.
- Infected HCWs who adhere to universal precautions and who perform certain exposure-prone procedures (see page 4) pose a small risk for transmitting HBV to patients.
- HIV is transmitted much less readily than HBV.

In the interim, until further data are available, additional precautions are prudent to prevent HIV and HBV transmission during procedures that have been linked to HCW-to-patient HBV transmission or that are considered exposure-prone.

BACKGROUND

Infection-Control Practices

Previous recommendations have specified that infection-control programs should incorporate principles of universal precautions (i.e., appropriate use of hand washing, protective barriers, and care in the use and disposal of needles and other sharp instruments) and should maintain these precautions rigorously in all health-care settings (1,2,5). Proper application of these principles will assist in minimizing the risk of transmission of HIV or HBV from patient to HCW, HCW to patient, or patient to patient.

As part of standard infection-control practice, instruments and other reusable equipment used in performing invasive procedures should be appropriately disinfected and sterilized as follows (7):

- Equipment and devices that enter the patient's vascular system or other normally sterile areas of the body should be sterilized before being used for each patient.
- Equipment and devices that touch intact mucous membranes but do not penetrate the patient's body surfaces should be sterilized when possible or undergo high-level disinfection if they cannot be sterilized before being used for each patient.
- Equipment and devices that do not touch the patient or that only touch intact skin of the patient need only be cleaned with a detergent or as indicated by the manufacturer.

Compliance with universal precautions and recommendations for disinfection and sterilization of medical devices should be scrupulously monitored in all health-care settings (1, 7, 8). Training of HCWs in proper infection-control technique should begin in professional and vocational schools and continue as an ongoing process. Institutions should provide all HCWs with appropriate inservice education regarding infection control and safety and should establish procedures for monitoring compliance with infection-control policies.

All HCWs who might be exposed to blood in an occupational setting should receive hepatitis B vaccine, preferably during their period of professional training and before any occupational exposures could occur (8, 9).

Transmission of HBV During Invasive Procedures

Since the introduction of serologic testing for HBV infection in the early 1970s, there have been published reports of 20 clusters in which a total of over 300 patients were infected with HBV in association with treatment by an HBV-infected HCW. In 12 of these clusters, the implicated HCW did not routinely wear gloves; several HCWs also had skin lesions that may have facilitated HBV transmission (10-22). These 12 clusters included nine linked to dentists or oral surgeons and one cluster each linked to a general practitioner, an inhalation therapist, and a cardiopulmonary-bypass-pump technician. The clusters associated with the inhalation therapist and the cardiopulmonary-bypass-pump technician—and some of the other 10 clusters—could possibly have been prevented if current recommendations on universal precautions, including glove use, had been in effect. In the remaining eight clusters, transmission occurred despite glove use by the HCWs; five clusters were linked to obstetricians or gynecologists, and three were linked to cardiovascular surgeons (6, 22-28). In addition, recent unpublished reports strongly suggest HBV transmission from three surgeons to patients in 1989 and 1990 during colorectal (CDC, unpublished data), abdominal, and cardiothoracic surgery (29).

Seven of the HCWs who were linked to published clusters in the United States were allowed to perform invasive procedures following modification of invasive techniques (e.g., double gloving and restriction of certain high-risk procedures) (6, 11-13, 15, 16, 24). For five HCWs, no further transmission to patients was observed. In two instances involving an obstetrician/gynecologist and an oral surgeon, HBV was transmitted to patients after techniques were modified (6, 12).

Review of the 20 published studies indicates that a combination of risk factors accounted for transmission of HBV from HCWs to patients. Of the HCWs whose hepatitis B e antigen (HBeAg) status was determined (17 of 20), all were HBeAg positive. The presence of HBeAg in serum is associated with higher levels of circulating virus and therefore with greater infectivity of hepatitis-B-surface-antigen (HBsAg)-positive individuals; the risk of HBV transmission to an HCW after a percutaneous exposure to HBeAg-positive blood is approximately 30% (30-32). In addition, each report indicated that the potential existed for contamination of surgical wounds or traumatized tissue, either from a major break in standard infection-control practices (e.g., not wearing gloves during invasive procedures) or from unintentional injury to the infected HCW during invasive procedures (e.g., needle sticks incurred while manipulating needles without being able to see them during suturing).

Most reported clusters in the United States occurred before awareness increased of the risks of transmission of blood-borne pathogens in health-care settings and before emphasis was placed on the use of universal precautions and hepatitis B vaccine among HCWs. The limited number of reports of HBV transmission from HCWs to patients in recent years may reflect the adoption of universal precautions and increased use of HBV vaccine. However, the limited number of recent reports does not preclude the occurrence of undetected or unreported small clusters or individual instances of

transmission; routine use of gloves does not prevent most injuries caused by sharp instruments and does not eliminate the potential for exposure of a patient to an HCW's blood and transmission of HBV (6, 22-29).

Transmission of HIV During Invasive Procedures

The risk of HIV transmission to an HCW after percutaneous exposure to HIV-infected blood is considerably lower than the risk of HBV transmission after percutaneous exposure to HBeAg-positive blood (0.3% versus approximately 30%) (33-35). Thus, the risk of transmission of HIV from an infected HCW to a patient during an invasive procedure is likely to be proportionately lower than the risk of HBV transmission from an HBeAg-positive HCW to a patient during the same procedure. As with HBV, the relative infectivity of HIV probably varies among individuals and over time for a single individual. Unlike HBV infection, however, there is currently no readily available laboratory test for increased HIV infectivity.

Investigation of a cluster of HIV infections among patients in the practice of one dentist with acquired immunodeficiency syndrome (AIDS) strongly suggested that HIV was transmitted to five of the approximately 850 patients evaluated through June 1991 (36-38). The investigation indicates that HIV transmission occurred during dental care, although the precise mechanisms of transmission have not been determined. In two other studies, when patients cared for by a general surgeon and a surgical resident who had AIDS were tested, all patients tested, 75 and 62, respectively, were negative for HIV infection (39, 40). In a fourth study, 143 patients who had been treated by a dental student with HIV infection and were later tested were all negative for HIV infection (41). In another investigation, HIV antibody testing was offered to all patients whose surgical procedures had been performed by a general surgeon within 7 years before the surgeon's diagnosis of AIDS; the date at which the surgeon became infected with HIV is unknown (42). Of 1,340 surgical patients contacted, 616 (46%) were tested for HIV. One patient, a known intravenous drug user, was HIV positive when tested but may already have been infected at the time of surgery. HIV test results for the 615 other surgical patients were negative (95% confidence interval for risk of transmission per operation = 0.0%-0.5%).

The limited number of participants and the differences in procedures associated with these five investigations limit the ability to generalize from them and to define precisely the risk of HIV transmission from HIV-infected HCWs to patients. A precise estimate of the risk of HIV transmission from infected HCWs to patients can be determined only after careful evaluation of a substantially larger number of patients whose exposure-prone procedures have been performed by HIV-infected HCWs.

Exposure-Prone Procedures

Despite adherence to the principles of universal precautions, certain invasive surgical and dental procedures have been implicated in the transmission of HBV from infected HCWs to patients, and should be considered exposure-prone. Reported examples include certain oral, cardiothoracic, colorectal (CDC, unpublished data), and obstetric/gynecologic procedures (6, 12, 22-29).

Certain other invasive procedures should also be considered exposure-prone. In a prospective study CDC conducted in four hospitals, one or more percutaneous injuries occurred among surgical personnel during 96 (6.9%) of 1,382 operative procedures on the general surgery, gynecology, orthopedic, cardiac, and trauma services (43). Percutaneous exposure of the patient to the HCW's blood may have occurred when the sharp object causing the injury recontacted the patient's open wound in 28 (32%) of the 88 observed injuries to surgeons (range among surgical specialties = 8%-57%; range among hospitals = 24%-42%).

Characteristics of exposure-prone procedures include digital palpation of a needle tip in a body cavity or the simultaneous presence of the HCW's fingers and a needle or other sharp instrument or object in a poorly visualized or highly confined anatomic site. Performance of exposure-prone procedures presents a recognized risk of percutaneous injury to the HCW, and—if such an injury occurs—the HCW's blood is likely to contact the patient's body cavity, subcutaneous tissues, and/or mucous membranes.

Experience with HBV indicates that invasive procedures that do not have the above characteristics would be expected to pose substantially lower risk, if any, of transmission of HIV and other blood-borne pathogens from an infected HCW to patients.

RECOMMENDATIONS

Investigations of HIV and HBV transmission from HCWs to patients indicate that, when HCWs adhere to recommended infection-control procedures, the risk of transmitting HBV from an infected HCW to a patient is small, and the risk of transmitting HIV is likely to be even smaller. However, the likelihood of exposure of the patient to an HCW's blood is greater for certain procedures designated as exposure-prone. To minimize the risk of HIV or HBV transmission, the following measures are recommended:

- All HCWs should adhere to universal precautions, including the appropriate use of hand washing, protective barriers, and care in the use and disposal of needles and other sharp instruments. HCWs who have exudative lesions or weeping dermatitis should refrain from all direct patient care and from handling patient-care equipment and devices used in performing invasive procedures until the condition resolves. HCWs should also comply with current guidelines for disinfection and sterilization of reusable devices used in invasive procedures.
- Currently available data provide no basis for recommendations to restrict the practice of HCWs infected with HIV or HBV who perform invasive procedures not identified as exposure-prone, provided the infected HCWs practice recommended surgical or dental technique and comply with universal precautions and current recommendations for sterilization/disinfection.
- Exposure-prone procedures should be identified by medical/surgical/dental organizations and institutions at which the procedures are performed.
- HCWs who perform exposure-prone procedures should know their HIV antibody status. HCWs infected with HIV or HBV who perform invasive procedures not identified as exposure-prone, provided the infected HCWs practice recommended surgical or dental technique and comply with universal precautions and current recommendations for sterilization/disinfection.
- HCWs who are infected with HIV or HBV (and are HBeAg positive) should not perform exposure-prone procedures unless they have sought counsel from an expert review panel and been advised under what circumstances, if any, they may continue to perform these procedures.* Such circumstances would include notifying prospective patients of the HCW's seropositivity before they undergo exposure-prone invasive procedures.
- Mandatory testing of HCWs for HIV antibody, HBsAg, or HBeAg is not recommended. The current assessment of the risk that infected HCWs will transmit HIV or HBV to patients during exposure-prone procedures does not support the diversion of resources that would be required to implement mandatory testing programs. Compliance by HCWs with recommendations can be increased through education, training, and appropriate confidentiality safeguards.

HCWS WHOSE PRACTICES ARE MODIFIED BECAUSE OF HIV OR HBV STATUS

HCWs whose practices are modified because of their HIV or HBV infection status should, whenever possible, be provided opportunities to continue appropriate patient-care activities. Career counseling and job retraining should be encouraged to promote the continued use of the HCW's talents, knowledge, and skills. HCWs whose practices are modified because of HBV infection should be reevaluated periodically to determine whether their HBeAg status changes due to resolution of infection or as a result of treatment (44).

*The review panel should include experts who represent a balanced perspective. Such experts might include all of the following: a) the HCW's personal physician(s), b) an infectious disease specialist with expertise in the epidemiology of HIV and HBV transmission, c) a health professional with expertise in the procedures performed by the HCW, and d) state or local public health official(s). If the HCW's practice is institutionally based, the expert review panel might also include a member of the infection-control committee, preferably a hospital epidemiologist. HCWs who perform exposure-prone procedures outside the hospital/institutional setting should seek advice from appropriate state and local public health officials regarding the review process. Panels must recognize the importance of confidentiality and the privacy rights of infected HCWs.

NOTIFICATION OF PATIENTS AND FOLLOW-UP STUDIES

The public health benefit of notification of patients who have had exposure-prone procedures performed by HCWs infected with HIV or positive for HBeAg should be considered on a case-by-case basis, taking into consideration an assessment of specific risks, confidentiality issues, and available resources. Carefully designed and implemented follow-up studies are necessary to determine more precisely the risk of transmission during such procedures. Decisions regarding notification and follow-up studies should be made in consultation with state and local public health officials.

ADDITIONAL NEEDS

- Clearer definition of the nature, frequency, and circumstances of blood contact between patients and HCWs during invasive procedures.
- Development and evaluation of new devices, protective barriers, and techniques that may prevent such blood contact without adversely affecting the quality of patient care.
- More information on the potential for HIV and HBV transmission through contaminated instruments.
- Improvements in sterilization and disinfection techniques for certain reusable equipment and devices.
- Identification of factors that may influence the likelihood of HIV or HBV transmission after exposure to HIV- or HBV-infected blood.

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APPENDIX

Definition of Invasive Procedure

An invasive procedure is defined as "surgical entry into tissues, cavities, or organs or repair of major traumatic injuries" associated with any of the following: "1) an operating or delivery room, emergency department, or outpatient setting, including both physicians' and dentists' offices; 2) cardiac catheterization and angiographic procedures; 3) a vaginal or cesarean delivery or other invasive obstetric procedure during which bleeding may occur; or 4) the manipulation, cutting, or removal of any oral or perioral tissues, including tooth structure, during which bleeding occurs or the potential for bleeding exists."

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Guidelines for Prevention of Transmission of Human Immunodeficiency Virus and Hepatitis B Virus to Health-Care and Public-Safety Workers

**A Response to P.L. 100-607
The Health Omnibus Programs Extension
Act of 1988**

**U.S. Department of Health and Human Services
Public Health Service
Centers for Disease Control
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TABLE OF CONTENTS

I. Introduction	3
A. Background	3
B. Purpose and Organization of Document	3
C. Modes and Risk of Virus Transmission in the Workplace	4
D. Transmission of Hepatitis B Virus to Workers	5
1. Health-care workers	5
2. Emergency medical and public-safety workers	6
3. Vaccination for hepatitis B virus	6
E. Transmission of Human Immunodeficiency Virus to Workers	6
1. Health-care workers with AIDS	6
2. Human immunodeficiency virus transmission in the workplace	7
3. Emergency medical service and public-safety workers	8
II. Principles of Infection Control and Their Application to Emergency and Public-Safety Workers	9
A. General Infection Control	9
B. Universal Blood and Body Fluid Precautions to Prevent Occupational HIV and HBV Transmission	9
III. Employer Responsibilities	11
A. General	11
B. Medical	12
1. Hepatitis B vaccination	12
2. Management of percutaneous exposure to blood and other infectious body fluids	12
a. Hepatitis B virus postexposure management	12
b. Human immunodeficiency virus postexposure management	13
3. Management of human bites	14
4. Documentation of exposure and reporting	14
5. Management of HBV- or HIV-infected workers	15
C. Disinfection, Decontamination, and Disposal	15
1. Needle and sharps disposal	16
2. Hand washing	16
3. Cleaning, disinfecting, and sterilizing	16
4. Cleaning and decontaminating spills of blood	16
5. Laundry	17
6. Decontamination and laundering of protective clothing	17
7. Infective waste	17
IV. Fire and Emergency Medical Services	19
A. Personal Protective Equipment	19
1. Gloves	19

2. Masks, eyewear, and gowns	20
3. Resuscitation equipment	20
V. Law-Enforcement and Correctional-Facility Officers	22
A. Law-Enforcement and Correctional-Facilities Considerations	22
1. Fights and assaults	22
2. Cardiopulmonary resuscitation	23
B. Law-Enforcement Considerations	23
1. Searches and evidence handling	23
2. Handling deceased persons and body removal	25
3. Autopsies	25
4. Forensic laboratories	25
C. Correctional-Facility Considerations	26
1. Searches	26
2. Decontamination and disposal	27
VI. References	28
VII. Tables	31

**Guidelines for Prevention of
Transmission of
Human Immunodeficiency Virus
and
Hepatitis B Virus
to Health-Care and
Public-Safety Workers**

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I. Introduction

A. Background

This document is a response to recently enacted legislation, Public Law 100-607, The Health Omnibus Programs Extension Act of 1988, Title II, Programs with Respect to Acquired Immune Deficiency Syndrome ("AIDS Amendments of 1988"). Subtitle E, General Provisions, Section 253(a) of Title II specifies that "the Secretary of Health and Human Services, acting through the Director of the Centers for Disease Control, shall develop, issue, and disseminate guidelines to all health workers, public safety workers (including emergency response employees) in the United States concerning —

- (1) methods to reduce the risk in the workplace of becoming infected with the etiologic agent for acquired immune deficiency syndrome; and
- (2) circumstances under which exposure to such etiologic agent may occur."

It is further noted that "The Secretary [of Health and Human Services] shall transmit the guidelines issued under subsection (a) to the Secretary of Labor for use by the Secretary of Labor in the development of standards to be issued under the Occupational Safety and Health Act of 1970," and that "the Secretary, acting through the Director of the Centers for Disease Control, shall develop a model curriculum for emergency response employees with respect to the prevention of exposure to the etiologic agent for acquired immune deficiency syndrome during the process of responding to emergencies."

Following development of these guidelines and curriculum, "[t]he Secretary shall —

- (A) transmit to State public health officers copies of the guidelines and the model curriculum developed under paragraph (1) with the request that such officers disseminate such copies as appropriate throughout the State; and
- (B) make such copies available to the public."

B. Purpose and Organization of Document

The purpose of this document is to provide an overview of the modes of transmission of human immunodeficiency virus (HIV) in the workplace, an assessment of the risk of transmission under various assumptions, principles underlying the control of risk, and specific risk-control recommendations for employers and workers. This document also includes information on medical management of persons who have sustained an exposure at the workplace to these viruses (e.g., an emergency medical technicians who incur a needle-stick injury while performing professional duties). These guidelines are intended

for use by a technically informed audience. As noted above, a separate model curriculum based on the principles and practices discussed in this document is being developed for use in training workers and will contain less technical wording.

Information concerning the protection of workers against acquisition of the human immunodeficiency virus (HIV) while performing job duties, the virus that causes AIDS, is presented here. Information on hepatitis B virus (HBV) is also presented in this document on the basis of the following assumptions:

- the modes of transmission for hepatitis B virus (HBV) are similar to those of HIV,
- the potential for HBV transmission in the occupational setting is greater than for HIV,
- there is a larger body of experience relating to controlling transmission of HBV in the workplace, and
- general practices to prevent the transmission of HBV will also minimize the risk of transmission of HIV.

Blood-borne transmission of other pathogens not specifically addressed here will be interrupted by adherence to the precautions noted below. It is important to note that the implementation of control measures for HIV and HBV does not obviate the need for continued adherence to general infection-control principles and general hygiene measures (e.g., hand washing) for preventing transmission of other infectious diseases to both worker and client. General guidelines for control of these diseases have been published (1,2,3).

This document was developed primarily to provide guidelines for fire-service personnel, emergency medical technicians, paramedics (see section IV, page 19), and law-enforcement and correctional-facility personnel (see section V, page 22). Throughout the report, paramedics and emergency medical technicians are called "emergency medical workers" and fire-service, law-enforcement, and correctional-facility personnel, "public-safety workers." Previously issued guidelines address the needs of hospital-, laboratory-, and clinic-based health-care workers (4,5). A condensation of general guidelines for protection of workers from transmission of blood-borne pathogens, derived from the Joint Advisory Notice of the Departments of Labor and Health and Human Services (6), is provided in section III (see page 11).

C. Modes and Risk of Virus Transmission in the Workplace

Although the potential for HBV transmission in the workplace setting is greater than for HIV, the modes of transmission for these two viruses are similar. Both have been transmitted in occupational settings only by percutaneous inoculation or contact with an open

wound, nonintact (e.g., chapped, abraded, weeping, or dermatitic) skin, or mucous membranes to blood, blood-contaminated body fluids, or concentrated virus. Blood is the single most important source of HIV and HBV in the workplace setting. Protection measures against HIV and HBV for workers should focus primarily on preventing these types of exposures to blood as well as on delivery of HBV vaccination.

The risk of hepatitis B infection following a parenteral (i.e., needlestick or cut) exposure to blood is directly proportional to the probability that the blood contains hepatitis B surface antigen (HBsAg), the immunity status of the recipient, and on the efficiency of transmission (7). The probability of the source of the blood being HBsAg positive varies from 1 to 3 per thousand in the general population to 5%–15% in groups at high risk for HBV infection, such as immigrants from areas of high endemicity (China and Southeast Asia, sub-Saharan Africa, most Pacific islands, and the Amazon Basin); clients in institutions for the mentally retarded; intravenous drug users; homosexually active males; and household (sexual and non-sexual) contacts of HBV carriers. Of persons who have not had prior hepatitis B vaccination or postexposure prophylaxis, 6%–30% of persons who receive a needle-stick exposure from an HBsAg-positive individual will become infected (7).

The risk of infection with HIV following one needle-stick exposure to blood from a patient known to be infected with HIV is approximately 0.5% (4,5). This rate of transmission is considerably lower than that for HBV, probably as a result of the significantly lower concentrations of virus in the blood of HIV-infected persons. Table 1 (see page 31) presents theoretical data concerning the likelihood of infection given repeated needle-stick injuries involving patients whose HIV serostatus is unknown. Though inadequately quantified, the risk from exposure of nonintact skin or mucous membranes is likely to be far less than that from percutaneous inoculation.

D. Transmission of Hepatitis B Virus to Workers

1. Health-care workers

In 1987, the CDC estimated the total number of HBV infections in the United States to be 300,000 per year, with approximately 75,000 (25%) of infected persons developing acute hepatitis. Of these infected individuals, 18,000–30,000 (6%–10%) will become HBV carriers, at risk of developing chronic liver disease (chronic active hepatitis, cirrhosis, and primary liver cancer), and infectious to others.

CDC has estimated that 12,000 health-care workers whose jobs entail exposure to blood become infected with HBV each year, that 500–600 of them are hospitalized as a result of that infection, and that 700–1,200 of those infected become HBV carriers. Of the infected workers, approximately 250 will die (12–15 from fulminant hepatitis, 170–200 from cirrhosis, and 40–50 from liver cancer). Studies indicate that

10%–30% of health-care or dental workers show serologic evidence of past or present HBV infection.

2. Emergency medical and public-safety workers

Emergency medical workers have an increased risk for hepatitis B infection (8,9,10). The degree of risk correlates with the frequency and extent of blood exposure during the conduct of work activities. A few studies are available concerning risk of HBV infection for other groups of public-safety workers (law-enforcement personnel and correctional-facility workers), but reports that have been published do not document any increased risk for HBV infection (11,12,13). Nevertheless, in occupational settings in which workers may be routinely exposed to blood or other body fluids as described below, an increased risk for occupational acquisition of HBV infection must be assumed to be present.

3. Vaccination for hepatitis B virus

A safe and effective vaccine to prevent hepatitis B has been available since 1982. Vaccination has been recommended for health-care workers regularly exposed to blood and other body fluids potentially contaminated with HBV (7,14,15). In 1987, the Department of Health and Human Services and the Department of Labor stated that hepatitis B vaccine should be provided to all such workers at no charge to the worker (6).

Available vaccines stimulate active immunity against HBV infection and provide over 90% protection against hepatitis B for 7 or more years following vaccination (7). Hepatitis B vaccines also are 70–88% effective when given within 1 week after HBV exposure. Hepatitis B immune globulin (HBIG), a preparation of immunoglobulin with high levels of antibody to HBV (anti-HBs), provides temporary passive protection following exposure to HBV. Combination treatment with hepatitis B vaccine and HBIG is over 90% effective in preventing hepatitis B following a documented exposure (7).

E. Transmission of Human Immunodeficiency Virus to Workers

1. Health-care workers with AIDS

As of September 19, 1988, a total of 3,182 (5.1%) of 61,929 adults with AIDS, who had been reported to the CDC national surveillance system and for whom occupational information was available, reported being employed in a health-care setting. Of the health-care workers with AIDS, 95% reported high-risk behavior; for the remaining 5% (169 workers), the means of HIV acquisition was undetermined.

Of these 169 health-care workers with AIDS with undetermined risk, information is

incomplete for 28 (17%) because of death or refusal to be interviewed; 97 (57%) are still being investigated. The remaining 44 (26%) health-care workers were interviewed directly or had other follow-up information available. The occupations of these 44 were nine nursing assistants (20%); eight physicians (18%), four of whom were surgeons; eight housekeeping or maintenance workers (18%); six nurses (14%); four clinical laboratory technicians (9%); two respiratory therapists (5%); one dentist (2%); one paramedic (2%); one embalmer (2%); and four others who did not have contact with patients (9%). Eighteen of these 44 health-care workers reported parenteral and/or other non-needle-stick exposure to blood or other body fluids from patients in the 10 years preceding their diagnosis of AIDS. None of these exposures involved a patient with AIDS or known HIV infection, and HIV seroconversion of the health-care worker was not documented following a specific exposure.

2. Human immunodeficiency virus transmission in the workplace

As of July 31, 1988, 1,201 health-care workers had been enrolled and tested for HIV antibody in ongoing CDC surveillance of health-care workers exposed via needle stick or splashes to skin or mucous membranes to blood from patients known to be HIV-infected (16). Of 860 workers who had received needle-stick injuries or cuts with sharp objects (i.e., parenteral exposures) and whose serum had been tested for HIV antibody at least 180 days after exposure, 4 were positive, yielding a seroprevalence rate of 0.47%. Three of these individuals experienced an acute retroviral syndrome associated with documented seroconversion. Investigation revealed no nonoccupational risk factors for these three workers. Serum collected within 30 days of exposure was not available from the fourth person. This worker had an HIV-seropositive sexual partner, and heterosexual acquisition of infection cannot be excluded. None of the 103 workers who had contamination of mucous membranes or nonintact skin and whose serum had been tested at least 180 days after exposure developed serologic evidence of HIV infection.

Two other ongoing prospective studies assess the risk of nosocomial acquisition of HIV infection among health-care workers in the United States. As of April 1988, the National Institutes of Health had tested 983 health-care workers, 137 with documented needle-stick injuries and 345 health-care workers who had sustained mucous-membrane exposures to blood or other body fluids of HIV-infected patients; none had seroconverted (17) (one health-care worker who subsequently experienced an occupational HIV seroconversion has since been reported from NIH [18]). As of March 15, 1988, a similar study at the University of California of 212 health-care workers with 625 documented accidental parenteral exposures involving HIV-infected patients had identified one seroconversion following a needle stick (19). Prospective studies in the United Kingdom and Canada show no evidence of HIV

transmission among 220 health-care workers with parenteral, mucous-membrane, or cutaneous exposures (20,21).

In addition to the health-care workers enrolled in these longitudinal surveillance studies, case histories have been published in the scientific literature for 19 HIV-infected health-care workers (13 with documented seroconversion and 6 without documented seroconversion). None of these workers reported nonoccupational risk factors (see Table 2, pages 32, 33).

3. Emergency medical service and public-safety workers

In addition to the one paramedic with undetermined risk discussed above, three public-safety workers (law-enforcement officers) are classified in the undetermined risk group. Follow-up investigations of these workers could not determine conclusively if HIV infection was acquired during the performance of job duties.

II. Principles of Infection Control and Their Application to Emergency and Public-Safety Workers

A. General Infection Control

Within the health-care setting, general infection control procedures have been developed to minimize the risk of patient acquisition of infection from contact with contaminated devices, objects, or surfaces or of transmission of an infectious agent from health-care workers to patients (1,2,3). Such procedures also protect workers from the risk of becoming infected. General infection-control procedures are designed to prevent transmission of a wide range of microbiological agents and to provide a wide margin of safety in the varied situations encountered in the health-care environment.

General infection-control principles are applicable to other work environments where workers contact other individuals and where transmission of infectious agents may occur. The modes of transmission noted in the hospital and medical office environment are observed in the work situations of emergency and public-safety workers, as well. Therefore, the principles of infection control developed for hospital and other health-care settings are also applicable to these work situations. Use of general infection control measures, as adapted to the work environments of emergency and public-safety workers, is important to protect both workers and individuals with whom they work from a variety of infectious agents, not just HIV and HBV.

Because emergency and public-safety workers work in environments that provide inherently unpredictable risks of exposures, general infection-control procedures should be adapted to these work situations. Exposures are unpredictable, and protective measures may often be used in situations that do not appear to present risk. Emergency and public-safety workers perform their duties in the community under extremely variable conditions; thus, control measures that are simple and uniform across all situations have the greatest likelihood of worker compliance. Administrative procedures to ensure compliance also can be more readily developed than when procedures are complex and highly variable.

B. Universal Blood and Body Fluid Precautions to Prevent Occupational HIV and HBV Transmission

In 1985, CDC developed the strategy of "universal blood and body fluid precautions" to address concerns regarding transmission of HIV in the health-care setting (4). The concept, now referred to simply as "universal precautions" stresses that all patients should be assumed to be infectious for HIV and other blood-borne pathogens. In the hospital and other health-care setting, "universal precautions" should be followed when workers are exposed to blood, certain other body fluids (amniotic fluid, pericardial fluid, peritoneal fluid, pleural fluid, synovial fluid, cerebrospinal fluid, semen, and vaginal secretions), or any body fluid visibly contaminated with blood. Since HIV and HBV

transmission has not been documented from exposure to other body fluids (feces, nasal secretions, sputum, sweat, tears, urine, and vomitus), "universal precautions" do not apply to these fluids. Universal precautions also do not apply to saliva, except in the dental setting, where saliva is likely to be contaminated with blood (7).

For the purpose of this document, human "exposure" is defined as contact with blood or other body fluids to which universal precautions apply through percutaneous inoculation or contact with an open wound, nonintact skin, or mucous membrane during the performance of normal job duties. An "exposed worker" is defined, for the purposes of this document, as an individual exposed, as described above, while performing normal job duties.

The unpredictable and emergent nature of exposures encountered by emergency and public-safety workers may make differentiation between hazardous body fluids and those which are not hazardous very difficult and often impossible. For example, poor lighting may limit the worker's ability to detect visible blood in vomitus or feces. Therefore, when emergency medical and public-safety workers encounter body fluids under uncontrolled, emergency circumstances in which differentiation between fluid types is difficult, if not impossible, they should treat all body fluids as potentially hazardous.

The application of the principles of universal precautions to the situations encountered by these workers results in the development of guidelines (listed below) for work practices, use of personal protective equipment, and other protective measures. To minimize the risks of acquiring HIV and HBV during performance of job duties, emergency and public-safety workers should be protected from exposure to blood and other body fluids as circumstances dictate. Protection can be achieved through adherence to work practices designed to minimize or eliminate exposure and through use of personal protective equipment (i.e., gloves, masks, and protective clothing), which provide a barrier between the worker and the exposure source. In some situations, redesign of selected aspects of the job through equipment modifications or environmental control can further reduce risk. These approaches to primary prevention should be used together to achieve maximal reduction of the risk of exposure.

If exposure of an individual worker occurs, medical management, consisting of collection of pertinent medical and occupational history, provision of treatment, and counseling regarding future work and personal behaviors, may reduce risk of developing disease as a result of the exposure episode (22). Following episodic (or continuous) exposure, decontamination and disinfection of the work environment, devices, equipment, and clothing or other forms of personal protective equipment can reduce subsequent risk of exposures. Proper disposal of contaminated waste has similar benefits.

III. Employer Responsibilities

A. General

Detailed recommendations for employer responsibilities in protecting workers from acquisition of blood-borne diseases in the workplace have been published in the Department of Labor and Department of Health and Human Services Joint Advisory Notice and are summarized here (6). In developing programs to protect workers, employers should follow a series of steps: 1) classification of work activity, 2) development of standard operating procedures, 3) provision of training and education, 4) development of procedures to ensure and monitor compliance, and 5) workplace redesign. As a first step, every employer should classify work activities into one of three categories of potential exposure (see Table 3, page 34). Employers should make protective equipment available to all workers when they are engaged in Category I or II activities. Employers should ensure that the appropriate protective equipment is used by workers when they perform Category I activities.

As a second step, employers should establish a detailed work practices program that includes standard operating procedures (SOPs) for all activities having the potential for exposure. Once these SOPs are developed, an initial and periodic worker education program to assure familiarity with work practices should be provided to potentially exposed workers. No worker should engage in such tasks or activities before receiving training pertaining to the SOPs, work practices, and protective equipment required for that task. Examples of personal protective equipment for the prehospital setting (defined as a setting where delivery of emergency health care takes place away from a hospital or other health-care setting) are provided in Table 4 (page 35). (A curriculum for such training programs is being developed in conjunction with these guidelines and should be consulted for further information concerning such training programs.)

To facilitate and monitor compliance with SOPs, administrative procedures should be developed and records kept as described in the Joint Advisory Notice (6). Employers should monitor the workplace to ensure that required work practices are observed and that protective clothing and equipment are provided and properly used. The employer should maintain records documenting the administrative procedures used to classify job activities and copies of all SOPs for tasks or activities involving predictable or unpredictable exposure to blood or other body fluids to which universal precautions apply. In addition, training records, indicating the dates of training sessions, the content of those training sessions along with the names of all persons conducting the training, and the names of all those receiving training should also be maintained.

Whenever possible, the employers should identify devices and other approaches to modifying the work environment which will reduce exposure risk. Such approaches are desirable, since they don't require individual worker action or management activity. For example, jails and correctional facilities should have classification procedures that require

the segregation of offenders who indicate through their actions or words that they intend to attack correctional-facility staff with the intent of transmitting HIV or HBV.

B. Medical

In addition to the general responsibilities noted above, the employer has the specific responsibility to make available to the worker a program of medical management. This program is designed to provide for the reduction of risk of infection by HBV and for counseling workers concerning issues regarding HIV and HBV. These services should be provided by a licensed health professional. All phases of medical management and counseling should ensure that the confidentiality of the worker's and client's medical data is protected.

1. Hepatitis B vaccination

All workers whose jobs involve participation in tasks or activities with exposure to blood or other body fluids to which universal precautions apply (as defined above on page 9) should be vaccinated with hepatitis B vaccine.

2. Management of percutaneous exposure to blood and other infectious body fluids

Once an exposure has occurred (as defined above on page 10), a blood sample should be drawn after consent is obtained from the individual from whom exposure occurred and tested for hepatitis B surface antigen (HBsAg) and antibody to human immunodeficiency virus (HIV antibody). Local laws regarding consent for testing source individuals should be followed. Policies should be available for testing source individuals in situations where consent cannot be obtained (e.g., an unconscious patient). Testing of the source individual should be done at a location where appropriate pretest counseling is available; posttest counseling and referral for treatment should be provided. It is extremely important that all individuals who seek consultation for any HIV-related concerns receive counseling as outlined in the "Public Health Service Guidelines for Counseling and Antibody Testing to Prevent HIV Infection and AIDS" (22).

a. Hepatitis B virus postexposure management

For an exposure to a source individual found to be positive for HBsAg, the worker who has not previously been given hepatitis B vaccine should receive the vaccine series. A single dose of hepatitis B immune globulin (HBIG) is also recommended, if this can be given within 7 days of exposure. For exposures from an HBsAg-positive source to workers who have previously received vaccine, the exposed worker should be tested for antibody to hepatitis B surface antigen (anti-HBs), and given one dose of vaccine and one dose

of HBIG if the antibody level in the worker's blood sample is inadequate (i.e., < 10 SRU by RIA, negative by ELA) (7).

If the source individual is negative for HBsAg and the worker has not been vaccinated, this opportunity should be taken to provide hepatitis B vaccination.

If the source individual refuses testing or he/she cannot be identified, the unvaccinated worker should receive the hepatitis B vaccine series. HBIG administration should be considered on an individual basis when the source individual is known or suspected to be at high risk of HBV infection. Management and treatment, if any, of previously vaccinated workers who receive an exposure from a source who refuses testing or is not identifiable should be individualized (7).

b. Human immunodeficiency virus postexposure management

For any exposure to a source individual who has AIDS, who is found to be positive for HIV infection (4), or who refuses testing, the worker should be counseled regarding the risk of infection and evaluated clinically and serologically for evidence of HIV infection as soon as possible after the exposure. In view of the evolving nature of HIV postexposure management, the health-care provider should be well informed of current PHS guidelines on this subject. The worker should be advised to report and seek medical evaluation for any acute febrile illness that occurs within 12 weeks after the exposure. Such an illness, particularly one characterized by fever, rash, or lymphadenopathy, may be indicative of recent HIV infection. Following the initial test at the time of exposure, seronegative workers should be retested 6 weeks, 12 weeks, and 6 months after exposure to determine whether transmission has occurred. During this follow-up period (especially the first 6-12 weeks after exposure, when most infected persons are expected to seroconvert), exposed workers should follow U.S. Public Health Service (PHS) recommendations for preventing transmission of HIV (22). These include refraining from blood donation and using appropriate protection during sexual intercourse (23). During all phases of follow-up, it is vital that worker confidentiality be protected.

If the source individual was tested and found to be seronegative, baseline testing of the exposed worker with follow-up testing 12 weeks later may be performed if desired by the worker or recommended by the health-care provider.

If the source individual cannot be identified, decisions regarding appropriate follow-up should be individualized. Serologic testing should be made available by the employer to all workers who may be concerned they have been infected with HIV through an occupational exposure as defined above (see page 10).

3. Management of human bites

On occasion, police and correctional-facility officers are intentionally bitten by suspects or prisoners. When such bites occur, routine medical and surgical therapy (including an assessment of tetanus vaccination status) should be implemented as soon as possible, since such bites frequently result in infection with organisms other than HIV and HBV. Victims of bites should be evaluated as described above (see page 12) for exposure to blood or other infectious body fluids.

Saliva of some persons infected with HBV has been shown to contain HBV-DNA at concentrations 1/1,000 to 1/10,000 of that found in the infected person's serum (5,24). HbsAg-positive saliva has been shown to be infectious when injected into experimental animals and in human bite exposures (25-27). However, HBsAg-positive saliva has not been shown to be infectious when applied to oral mucous membranes in experimental primate studies (27) or through contamination of musical instruments or cardiopulmonary resuscitation dummies used by HBV carriers (28,29). Epidemiologic studies of nonsexual household contacts of HIV-infected patients, including several small series in which HIV transmission failed to occur after bites or after percutaneous inoculation or contamination of cuts and open wounds with saliva from HIV-infected patients, suggest that the potential for salivary transmission of HIV is remote (5,30-33). One case report from Germany has suggested the possibility of transmission of HIV in a household setting from an infected child to a sibling through a human bite (34). The bite did not break the skin or result in bleeding. Since the date of seroconversion to HIV was not known for either child in this case, evidence for the role of saliva in the transmission of virus is unclear (34.)

4. Documentation of exposure and reporting

As part of the confidential medical record, the circumstances of exposure should be recorded. Relevant information includes the activity in which the worker was engaged at the time of exposure, the extent to which appropriate work practices and protective equipment were used, and a description of the source of exposure.

Employers have a responsibility under various federal and state laws and regulations to report occupational illnesses and injuries. Existing programs in the National Institute for Occupational Safety and Health (NIOSH), Department of Health and Human Services; the Bureau of Labor Statistics, Department of Labor (DOL); and the Occupational Safety and Health Administration (DOL) receive such information

for the purposes of surveillance and other objectives. Cases of infectious disease, including AIDS and HBV infection, are reported to the Centers for Disease Control through State health departments.

5. Management of HBV- or HIV-infected workers

Transmission of HBV from health-care workers to patients has been documented. Such transmission has occurred during certain types of invasive procedures (e.g., oral and gynecologic surgery) in which health-care workers, when tested, had very high concentrations of HBV in their blood (at least 100 million infectious virus particles per milliliter, a concentration much higher than occurs with HIV infection), and the health-care workers sustained a puncture wound while performing invasive procedures or had exudative or weeping lesions or microlacerations that allowed virus to contaminate instruments or open wounds of patients (35,36). A worker who is HBsAg positive and who has transmitted hepatitis B virus to another individual during the performance of his or her job duties should be excluded from the performance of those job duties which place other individuals at risk for acquisition of hepatitis B infection.

Workers with impaired immune systems resulting from HIV infection or other causes are at increased risk of acquiring or experiencing serious complications of infectious disease. Of particular concern is the risk of severe infection following exposure to other persons with infectious diseases that are easily transmitted if appropriate precautions are not taken (e.g., measles, varicella). Any worker with an impaired immune system should be counseled about the potential risk associated with providing health care to persons with any transmissible infection and should continue to follow existing recommendations for infection control to minimize risk of exposure to other infectious agents (2,3). Recommendations of the Immunization Practices Advisory Committee (ACIP) and institutional policies concerning requirements for vaccinating workers with live-virus vaccines (e.g., measles, rubella) should also be considered.

The question of whether workers infected with HIV can adequately and safely be allowed to perform patient-care duties or whether their work assignments should be changed must be determined on an individual basis. These decisions should be made by the worker's personal physician(s) in conjunction with the employer's medical advisors.

C. Disinfection, Decontamination, and Disposal

As described in Section I.C. (see page 4), the only documented occupational risks of HIV and HBV infection are associated with parenteral (including open wound) and mucous membrane exposure to blood and other potentially infectious body fluids. Nevertheless, the precautions described below should be routinely followed.

1. Needle and sharps disposal

All workers should take precautions to prevent injuries caused by needles, scalpels, and other sharp instruments or devices during procedures; when cleaning used instruments; during disposal of used needles; and when handling sharp instruments after procedures. To prevent needle-stick injuries, needles should not be recapped, purposely bent or broken by hand, removed from disposable syringes, or otherwise manipulated by hand. After they are used, disposable syringes and needles, scalpel blades, and other sharp items should be placed in puncture-resistant containers for disposal; the puncture-resistant containers should be located as close as practical to the use area (e.g., in the ambulance or, if sharps are carried to the scene of victim assistance from the ambulance, a small puncture-resistant container should be carried to the scene, as well). Reusable needles should be left on the syringe body and should be placed in a puncture-resistant container for transport to the reprocessing area.

2. Hand washing

Hands and other skin surfaces should be washed immediately and thoroughly if contaminated with blood, other body fluids to which universal precautions apply, or potentially contaminated articles. Hands should always be washed after gloves are removed, even if the gloves appear to be intact. Hand washing should be completed using the appropriate facilities, such as utility or restroom sinks. Waterless antiseptic hand cleanser should be provided on responding units to use when hand-washing facilities are not available. When hand-washing facilities are available, wash hands with warm water and soap. When hand-washing facilities are not available, use a waterless antiseptic hand cleanser. The manufacturer's recommendations for the product should be followed.

3. Cleaning, disinfecting, and sterilizing

Table 5 (see pages 36, 37) presents the methods and applications for cleaning, disinfecting, and sterilizing equipment and surfaces in the prehospital setting. These methods also apply to housekeeping and other cleaning tasks. Previously issued guidelines for health-care workers contain more detailed descriptions (4).

4. Cleaning and decontaminating spills of blood

All spills of blood and blood-contaminated fluids should be promptly cleaned up using an EPA-approved germicide or a 1:100 solution of household bleach in the following manner **while wearing gloves**. Visible material should first be removed with disposable towels or other appropriate means that will ensure against direct contact with blood. If splashing is anticipated, protective eyewear should be worn along with an impervious gown or apron which provides an effective barrier to splashes. The

area should then be decontaminated with an appropriate germicide. Hands should be washed following removal of gloves. Soiled cleaning equipment should be cleaned and decontaminated or placed in an appropriate container and disposed of according to agency policy. Plastic bags should be available for removal of contaminated items from the site of the spill.

Shoes and boots can become contaminated with blood in certain instances. Where there is massive blood contamination on floors, the use of disposable impervious shoe coverings should be considered. Protective gloves should be worn to remove contaminated shoe coverings. The coverings and gloves should be disposed of in plastic bags. A plastic bag should be included in the crime scene kit or the car which is to be used for the disposal of contaminated items. Extra plastic bags should be stored in the police cruiser or emergency vehicle.

5. Laundry

Although soiled linen may be contaminated with pathogenic microorganisms, the risk of actual disease transmission is negligible. Rather than rigid procedures and specifications, hygienic storage and processing of clean and soiled linen are recommended. Laundry facilities and/or services should be made routinely available by the employer. Soiled linen should be handled as little as possible and with minimum agitation to prevent gross microbial contamination of the air and of persons handling the linen. All soiled linen should be bagged at the location where it was used. Linen soiled with blood should be placed and transported in bags that prevent leakage. Normal laundry cycles should be used according to the washer and detergent manufacturers' recommendations.

6. Decontamination and laundering of protective clothing

Protective work clothing contaminated with blood or other body fluids to which universal precautions apply should be placed and transported in bags or containers that prevent leakage. Personnel involved in the bagging, transport, and laundering of contaminated clothing should wear gloves. Protective clothing and station and work uniforms should be washed and dried according to the manufacturer's instructions. Boots and leather goods may be brush-scrubbed with soap and hot water to remove contamination.

7. Infective waste

The selection of procedures for disposal of infective waste is determined by the relative risk of disease transmission and application of local regulations, which vary widely. **In all cases, local regulations should be consulted prior to disposal procedures and followed.** Infective waste, in general, should either be incinerated or should be decontaminated before disposal in a sanitary landfill. Bulk blood, suctioned

fluids, excretions, and secretions may be carefully poured down a drain connected to a sanitary sewer, where permitted. Sanitary sewers may also be used to dispose of other infectious wastes capable of being ground and flushed into the sewer, where permitted. Sharp items should be placed in puncture-proof containers and other blood-contaminated items should be placed in leak-proof plastic bags for transport to an appropriate disposal location.

Prior to the removal of protective equipment, personnel remaining on the scene after the patient has been cared for should carefully search for and remove contaminated materials. Debris should be disposed of as noted above.

IV. Fire and Emergency Medical Services

The guidelines that appear in this section apply to fire and emergency medical services. This includes structural fire fighters, paramedics, emergency medical technicians, and advanced life support personnel. Fire fighters often provide emergency medical services and therefore encounter the exposures common to paramedics and emergency medical technicians. Job duties are often performed in uncontrolled environments, which, due to a lack of time and other factors, do not allow for application of a complex decision-making process to the emergency at hand.

The general principles presented here have been developed from existing principles of occupational safety and health in conjunction with data from studies of health-care workers in hospital settings. The basic premise is that workers must be protected from exposure to blood and other potentially infectious body fluids in the course of their work activities. There is a paucity of data concerning the risks these worker groups face, however, which complicates development of control principles. Thus, the guidelines presented below are based on principles of prudent public health practice.

Fire and emergency medical service personnel are engaged in delivery of medical care in the prehospital setting. The following guidelines are intended to assist these personnel in making decisions concerning use of personal protective equipment and resuscitation equipment, as well as for decontamination, disinfection, and disposal procedures.

A. Personal Protective Equipment

Appropriate personal protective equipment should be made available routinely by the employer to reduce the risk of exposure as defined above. For many situations, the chance that the rescuer will be exposed to blood and other body fluids to which universal precautions apply can be determined in advance. Therefore, if the chances of being exposed to blood is high (e.g., CPR, IV insertion, trauma, delivering babies), the worker should put on protective attire before beginning patient care. Table 4 (see page 35) sets forth examples of recommendations for personal protective equipment in the prehospital setting; the list is not intended to be all-inclusive.

1. Gloves

Disposable gloves should be a standard component of emergency response equipment, and should be donned by all personnel prior to initiating any emergency patient care tasks involving exposure to blood or other body fluids to which universal precautions apply. Extra pairs should always be available. Considerations in the choice of disposable gloves should include dexterity, durability, fit, and the task being performed. Thus, there is no single type or thickness of glove appropriate for protection in all situations. For situations where large amounts of blood are likely to be encountered, it is important that gloves fit tightly at the wrist to prevent blood contamination

of hands around the cuff. For multiple trauma victims, gloves should be changed between patient contacts, if the emergency situation allows.

Greater personal protective equipment measures are indicated for situations where broken glass and sharp edges are likely to be encountered, such as extricating a person from an automobile wreck. Structural fire-fighting gloves that meet the Federal OSHA requirements for fire-fighters gloves (as contained in 29 CFR 1910.156 or National Fire Protection Association Standard 1973, Gloves for Structural Fire Fighters) should be worn in any situation where sharp or rough surfaces are likely to be encountered (37).

While wearing gloves, avoid handling personal items, such as combs and pens, that could become soiled or contaminated. Gloves that have become contaminated with blood or other body fluids to which universal precautions apply should be removed as soon as possible, taking care to avoid skin contact with the exterior surface. Contaminated gloves should be placed and transported in bags that prevent leakage and should be disposed of or, in the case of reusable gloves, cleaned and disinfected properly.

2. Masks, eyewear, and gowns

Masks, eyewear, and gowns should be present on all emergency vehicles that respond or potentially respond to medical emergencies or victim rescues. These protective barriers should be used in accordance with the level of exposure encountered. Minor lacerations or small amounts of blood do not merit the same extent of barrier use as required for exsanguinating victims or massive arterial bleeding. Management of the patient who is not bleeding, and who has no bloody body fluids present, should not routinely require use of barrier precautions. Masks and eyewear (e.g., safety glasses) should be worn together, or a faceshield should be used by all personnel prior to any situation where splashes of blood or other body fluids to which universal precautions apply are likely to occur. Gowns or aprons should be worn to protect clothing from splashes with blood. If large splashes or quantities of blood are present or anticipated, impervious gowns or aprons should be worn. An extra change of work clothing should be available at all times.

3. Resuscitation equipment

No transmission of HBV or HIV infection during mouth-to-mouth resuscitation has been documented. However, because of the risk of salivary transmission of other infectious diseases (e.g., herpes simplex and *Neisseria meningitidis*) and the theoretical risk of HIV and HBV transmission during artificial ventilation of trauma victims, disposable airway equipment or resuscitation bags should be used. Disposable resuscitation equipment and devices should be used once and disposed of or, if reusable,

thoroughly cleaned and disinfected after each use according to the manufacturer's recommendations.

Mechanical respiratory assist devices (e.g., bag-valve masks, oxygen demand valve resuscitators) should be available on all emergency vehicles and to all emergency response personnel that respond or potentially respond to medical emergencies or victim rescues.

Pocket mouth-to-mouth resuscitation masks designed to isolate emergency response personnel (i.e., double lumen systems) from contact with victims' blood and blood-contaminated saliva, respiratory secretions, and vomitus should be provided to all personnel who provide or potentially provide emergency treatment.

V. Law-Enforcement and Correctional-Facility Officers

Law-enforcement and correctional-facility officers may face the risk of exposure to blood during the conduct of their duties. For example, at the crime scene or during processing of suspects, law-enforcement officers may encounter blood-contaminated hypodermic needles or weapons, or be called upon to assist with body removal. Correctional-facility officers may similarly be required to search prisoners or their cells for hypodermic needles or weapons, or subdue violent and combative inmates.

The following section presents information for reducing the risk of acquiring HIV and HBV infection by law-enforcement and correctional-facility officers as a consequence of carrying out their duties. However, there is an extremely diverse range of potential situations which may occur in the control of persons with unpredictable, violent, or psychotic behavior. Therefore, informed judgment of the individual officer is paramount when unusual circumstances or events arise. These recommendations should serve as an adjunct to rational decision making in those situations where specific guidelines do not exist, particularly where immediate action is required to preserve life or prevent significant injury.

The following guidelines are arranged into three sections: a section addressing concerns shared by both law-enforcement and correctional-facility officers, and two sections dealing separately with law-enforcement officers and correctional-facility officers, respectively. Table 4 (see page 35) contains selected examples of personal protective equipment that may be employed by law-enforcement and correctional-facility officers.

A. Law-Enforcement and Correctional-Facilities Considerations

1. Fights and assaults

Law-enforcement and correctional-facility officers are exposed to a range of assaultive and disruptive behavior through which they may potentially become exposed to blood or other body fluids containing blood. Behaviors of particular concern are biting, attacks resulting in blood exposure, and attacks with sharp objects. Such behaviors may occur in a range of law-enforcement situations including arrests, routine interrogations, domestic disputes, and lockup operations, as well as in correctional-facility activities. Hand-to-hand combat may result in bleeding and may thus incur a greater chance for blood-to-blood exposure, which increases the chances for blood-borne disease transmission.

Whenever the possibility for exposure to blood or blood-contaminated body fluids exists, the appropriate protection should be worn, if feasible under the circumstances. In all cases, extreme caution must be used in dealing with the suspect or prisoner if there is any indication of assaultive or combative behavior. When blood is present and a suspect or an inmate is combative or threatening to staff, gloves should always

be put on as soon as conditions permit. In case of blood contamination of clothing, an extra change of clothing should be available at all times.

2. Cardiopulmonary resuscitation

Law-enforcement and correctional personnel are also concerned about infection with HIV and HBV through administration of cardiopulmonary resuscitation (CPR). Although there have been no documented cases of HIV transmission through this mechanism, the possibility of transmission of other infectious diseases exists. Therefore, agencies should make protective masks or airways available to officers and provide training in their proper use. Devices with one-way valves to prevent the patients' saliva or vomitus from entering the caregiver's mouth are preferable.

B. Law-Enforcement Considerations

1. Searches and evidence handling

Criminal justice personnel have potential risks of acquiring HBV or HIV infection through exposures which occur during searches and evidence handling. Penetrating injuries are known to occur, and puncture wounds or needle sticks in particular pose a hazard during searches of persons, vehicles, or cells, and during evidence handling. The following precautionary measures will help to reduce the risk of infection:

- An officer should use great caution in searching the clothing of suspects. Individual discretion, based on the circumstances at hand, should determine if a suspect or prisoner should empty his own pockets or if the officer should use his own skills in determining the contents of a suspect's clothing.
- A safe distance should always be maintained between the officer and the suspect.
- Wear protective gloves if exposure to blood is likely to be encountered.
- Wear protective gloves for all body cavity searches.
- If cotton gloves are to be worn when working with evidence of potential latent fingerprint value at the crime scene, they can be worn over protective disposable gloves when exposure to blood may occur.
- Always carry a flashlight, even during daylight shifts, to search hidden areas. Whenever possible, use long-handled mirrors and flashlights to search such areas (e.g., under car seats).

- If searching a purse, carefully empty contents directly from purse, by turning it upside down over a table.
- Use puncture-proof containers to store sharp instruments and clearly marked plastic bags to store other possibly contaminated items.
- To avoid tearing gloves, use evidence tape instead of metal staples to seal evidence.
- Local procedures for evidence handling should be followed. In general, items should be air dried before sealing in plastic.

Not all types of gloves are suitable for conducting searches. Vinyl or latex rubber gloves provide little protection against sharp instruments, and they are not puncture-proof. There is a direct trade-off between level of protection and manipulability. In other words, the thicker the gloves, the more protection they provide, but the less effective they are in locating objects. Thus, there is no single type or thickness of glove appropriate for protection in all situations. Officers should select the type and thickness of glove which provides the best balance of protection and search efficiency.

Officers and crime scene technicians may confront unusual hazards, especially when the crime scene involves violent behavior, such as a homicide where large amounts of blood are present. Protective gloves should be available and worn in this setting. In addition, for very large spills, consideration should be given to other protective clothing, such as overalls, aprons, boots, or protective shoe covers. They should be changed if torn or soiled, and always removed prior to leaving the scene. While wearing gloves, avoid handling personal items, such as combs and pens, that could become soiled or contaminated.

Face masks and eye protection or a face shield are required for laboratory and evidence technicians whose jobs which entail potential exposures to blood via a splash to the face, mouth, nose, or eyes.

Airborne particles of dried blood may be generated when a stain is scraped. It is recommended that protective masks and eyewear or face shields be worn by laboratory or evidence technicians when removing the blood stain for laboratory analyses.

While processing the crime scene, personnel should be alert for the presence of sharp objects such as hypodermic needles, knives, razors, broken glass, nails, or other sharp objects.

2. Handling deceased persons and body removal

For detectives, investigators, evidence technicians, and others who may have to touch or remove a body, the response should be the same as for situations requiring CPR or first aid: wear gloves and cover all cuts and abrasions to create a barrier and carefully wash all exposed areas after any contact with blood. The precautions to be used with blood and deceased persons should also be used when handling amputated limbs, hands, or other body parts. Such procedures should be followed after contact with the blood of anyone, regardless of whether they are known or suspected to be infected with HIV or HBV.

3. Autopsies

Protective masks and eyewear (or face shields), laboratory coats, gloves, and waterproof aprons should be worn when performing or attending all autopsies. All autopsy material should be considered infectious for both HIV and HBV. Onlookers with an opportunity for exposure to blood splashes should be similarly protected. Instruments and surfaces contaminated during postmortem procedures should be decontaminated with an appropriate chemical germicide (4). Many laboratories have more detailed standard operating procedures for conducting autopsies; where available, these should be followed. More detailed recommendations for health-care workers in this setting have been published (4).

4. Forensic laboratories

Blood from all individuals should be considered infective. To supplement other worksite precautions, the following precautions are recommended for workers in forensic laboratories.

- a. All specimens of blood should be put in a well-constructed, appropriately labelled container with a secure lid to prevent leaking during transport. Care should be taken when collecting each specimen to avoid contaminating the outside of the container and of the laboratory form accompanying the specimen.
- b. All persons processing blood specimens should wear gloves. Masks and protective eyewear or face shields should be worn if mucous-membrane contact with blood is anticipated (e.g., removing tops from vacuum tubes). Hands should be washed after completion of specimen processing.
- c. For routine procedures, such as histologic and pathologic studies or microbiological culturing, a biological safety cabinet is not necessary. However, biological safety cabinets (Class I or II) should be used whenever procedures are conducted that have a high potential for generating droplets. These include activities such as blending, sonicating, and vigorous mixing.

- d. Mechanical pipetting devices should be used for manipulating all liquids in the laboratory. Mouth pipetting must not be done.
- e. Use of needles and syringes should be limited to situations in which there is no alternative, and the recommendations for preventing injuries with needles outlined under universal precautions should be followed.
- f. Laboratory work surfaces should be cleaned of visible materials and then decontaminated with an appropriate chemical germicide after a spill of blood, semen, or blood-contaminated body fluid and when work activities are completed.
- g. Contaminated materials used in laboratory tests should be decontaminated before reprocessing or be placed in bags and disposed of in accordance with institutional and local regulatory policies for disposal of infective waste.
- h. Scientific equipment that has been contaminated with blood should be cleaned and then decontaminated before being repaired in the laboratory or transported to the manufacturer.
- i. All persons should wash their hands after completing laboratory activities and should remove protective clothing before leaving the laboratory.
- j. Area posting of warning signs should be considered to remind employees of continuing hazard of infectious disease transmission in the laboratory setting.

C. Correctional-Facility Considerations

1. Searches

Penetrating injuries are known to occur in the correctional-facility setting, and puncture wounds or needle sticks in particular pose a hazard during searches of prisoners or their cells. The following precautionary measures will help to reduce the risk of infection:

- A correctional-facility officer should use great caution in searching the clothing of prisoners. Individual discretion, based on the circumstances at hand, should determine if a prisoner should empty his own pockets or if the officer should use his own skills in determining the contents of a prisoner's clothing.
- A safe distance should always be maintained between the officer and the prisoner.

- Always carry a flashlight, even during daylight shifts, to search hidden areas. Whenever possible, use long-handled mirrors and flashlights to search such areas (e.g., under commodes, bunks, and in vents in jail cells).
- Wear protective gloves if exposure to blood is likely to be encountered.
- ● Wear protective gloves for all body cavity searches.

Not all types of gloves are suitable for conducting searches. Vinyl or latex rubber gloves can provide little, if any, protection against sharp instruments, and they are not puncture-proof. There is a direct trade-off between level of protection and manipulability. In other words, the thicker the gloves, the more protection they provide, but the less effective they are in locating objects. Thus, there is no single type or thickness of glove appropriate for protection in all situations. Officers should select the type and thickness of glove which provides the best balance of protection and search efficiency.

2. Decontamination and disposal

Prisoners may spit at officers and throw feces; sometimes these substances have been purposefully contaminated with blood. Although there are no documented cases of HIV or HBV transmission in this manner and transmission by this route would not be expected to occur, other diseases could be transmitted. These materials should be removed with a paper towel after donning gloves, and the area then decontaminated with an appropriate germicide. Following clean-up, soiled towels and gloves should be disposed of properly.

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VII. Tables

Table 1. The Risk of HIV Infection
Following Needlestick Injury: Hypothetical Model

Prevalence of HIV Infection (A)	Probability of Infection Given Needlestick Injury with Blood Containing HIV (B)	Probability of Infection Given Random Needlestick (Unknown Serostatus) $A * B = (C)$	Probability of Infection Given 10 Random Needlesticks $1-(1-C)^{10}$	Probability of Infection Given 100 Random Needlesticks $1-(1-C)^{100}$
0.0001	0.001	0.0000001	0.000001	0.00001
0.0001	0.005	0.0000005	0.000005	0.00005
0.001	0.001	0.0000001	0.00001	0.0001
0.001	0.005	0.0000005	0.00005	0.0005
0.01	0.001	0.000001	0.0001	0.001
0.01*	0.005	0.000005	0.0005	0.005
0.05	0.001	0.000005	0.0005	0.005
0.05	0.005	0.000025	0.0025	0.025

* For example, if the prevalence of infection in the population is 0.01 (i.e., 1 per 100) and the risk of a seroconversion following a needlestick with blood known to contain HIV is 0.005 (i.e., 1 in 200), then the probability of HIV infection given a random needlestick is 0.00005 (i.e., 5 in 100,000). If an individual sustains 10 needlestick injuries, the probability of acquiring HIV infection is 0.0005 (i.e., 1 in 2,000); if the individual sustains 100 needlestick injuries, the probability of acquiring HIV infection is 0.005 (i.e., 1 in 200).

Table 2.
HIV-infected health-care workers with no reported nonoccupational
risk factors and for whom case histories have been
published in the scientific literature

Cases with Documented Seroconversion

Case	Occupation	Country	Type of Exposure	Source
1*	NS†	United States	Needlestick	AIDS patient
2	NS	United States	Needlestick	AIDS patient
3	NS	United States	Needlestick	AIDS patient
4	NS	United States	2 Needlesticks	AIDS patient, HIV-infected patient
5	NS	United States	Needlestick	AIDS patient
6	Nurse	England	Needlestick	AIDS patient
7	Nurse	France	Needlestick	HIV-infected patient
8	Nurse	Martinique	Needlestick	AIDS patient
9	Research lab worker	United States	Cut with sharp object	Concentrated virus
10	Home health- care worker	United States	Cutaneous#	AIDS patient
11	NS	United States	Nonintact skin	AIDS patient
12	Phlebotomist	United States	Mucous-membrane	HIV-infected patient
13	Technologist	United States	Nonintact skin	HIV-infected patient
14	NS	United States	Needlestick	AIDS patient
15	Nurse	Italy	Mucous membrane	HIV-infected patient
16	Nurse	France	Needlestick	AIDS patient
17	Navy medic	United States	Needlestick	AIDS patient
18	Clinical lab worker	United States	Cut with sharp object	AIDS patient

* AIDS case

† Not specified

Mother who provided nursing care for her child with HIV infection; extensive contact with the child's blood and body secretions and excretions occurred; the mother did not wear gloves and often did not wash her hands immediately after exposure.

Table 2, continued.
HIV-infected health-care workers with no reported nonoccupational
risk factors and for whom case histories have been published
in the scientific literature

Cases without Documented Seroconversion

Case	Occupation	Country	Type of Exposure	Source
19	NS	United States	Puncture wound	AIDS patient
20	NS	United States	2 Needlesticks	2 AIDS patients
21	Research lab worker	United States	Nonintact skin	Concentrated virus
22	Home health-care provider	England	Nonintact skin	AIDS patient
23	Dentist	United States	Multiple needlesticks	Unknown
24*	Technician	Mexico	Multiple needlesticks and mucous-membrane	Unknown
25	Lab worker	United States	Needlestick, puncture wound	Unknown

* AIDS case

Table 3. Summary of Task Categorization and Implications for Personal Protective Equipment

<u>Joint Advisory Notice Category¹</u>	<u>Nature of Task/Activity</u>	<u>Personal protective equipment should be:</u>	
		<u>Available?</u>	<u>Worn?</u>
I.	Direct contact with blood or other body fluids to which universal precautions apply	Yes	Yes
II.	Activity performed without blood exposure but exposure may occur in emergency	Yes	No
III.	Task/activity does not entail predictable or unpredictable exposure to blood	No	No

¹ U.S. Department of Labor, U.S. Department of Health and Human Services. Joint advisory notice: protection against occupational exposure to hepatitis B virus (HBV) and human immunodeficiency virus (HIV). Washington, DC: US Department of Labor, US Department of Health and Human Services, 1987.

Table 4. Examples of Recommended Personal Protective Equipment for Worker Protection Against HIV and HBV Transmission¹ in Prehospital² Settings

<u>Task or Activity</u>	<u>Disposable Gloves</u>	<u>Gown</u>	<u>Mask³</u>	<u>Protective Eyewear</u>
Bleeding control with with spurting blood	Yes	Yes	Yes	Yes
Bleeding control with minimal bleeding	Yes	No	No	No
Emergency childbirth	Yes	Yes	Yes, if splashing is likely	Yes, if splashing is likely
Blood drawing	At certain times ⁴	No	No	No
Starting an intravenous (IV) line	Yes	No	No	No
Endotracheal intubation, esophageal obturator use	Yes	No	No, unless splashing is likely	No, unless splashing is likely
Oral/nasal suctioning, manually cleaning airway	Yes ⁵	No	No, unless splashing is likely	No, unless splashing is likely
Handling and cleaning instruments with microbial contamination	Yes	No, unless soiling is likely	No	No
Measuring blood pressure	No	No	No	No
Measuring temperature	No	No	No	No
Giving an injection	No	No	No	No

¹The examples provided in this table are based on application of universal precautions. Universal precautions are intended to supplement rather than replace recommendations for routine infection control, such as handwashing and using gloves to prevent gross microbial contamination of hands (e.g., contact with urine or feces).

²Defined as setting where delivery of emergency health care takes place away from a hospital or other health-care facility.

³Refers to protective masks to prevent exposure of mucous membranes to blood or other potentially contaminated body fluids. The use of resuscitation devices, some of which are also referred to as "masks," is discussed on page 23.

⁴For clarification see Appendix A, page 7, and Appendix B, page 7.

⁵While not clearly necessary to prevent HIV or HBV transmission unless blood is present, gloves are recommended to prevent transmission of other agents (e.g., *Herpes simplex*).

Table 5. Reprocessing Methods for Equipment Used in the Prehospital Health-Care Setting

Sterilization:	Destroys:	All forms of microbial life including high numbers of bacterial spores.
	Methods:	Steam under pressure (autoclave), gas (ethylene oxide), dry heat, or immersion in EPA-approved chemical "sterilant" for prolonged period of time, e.g., 6–10 hours or according to manufacturers' instructions. Note: liquid chemical "sterilants" should be used only on those instruments that are impossible to sterilize or disinfect with heat.
	Use:	For those instruments or devices that penetrate skin or contact normally sterile areas of the body, e.g., scalpels, needles, etc. Disposable invasive equipment eliminates the need to reprocess these types of items. When indicated, however, arrangements should be made with a health-care facility for reprocessing of reusable invasive instruments.
High-Level Disinfection:	Destroys:	All forms of microbial life except high numbers of bacterial spores.
	Methods:	Hot water pasteurization (80–100 C, 30 minutes) or exposure to an EPA-registered "sterilant" chemical as above, except for a short exposure time (10–45 minutes or as directed by the manufacturer).
	Use:	For reusable instruments or devices that come into contact with mucous membranes (e.g., laryngoscope blades, endotracheal tubes, etc.).
Intermediate-Level Disinfection:	Destroys:	<i>Mycobacterium tuberculosis</i> , vegetative bacteria, most viruses, and most fungi, but does not kill bacterial spores.
	Methods:	EPA-registered "hospital disinfectant" chemical germicides that have a label claim for tuberculocidal activity; commercially available hard-surface germicides or solutions containing at least 500 ppm free available chlorine (a 1:100 dilution of common household bleach—a approximately ¼ cup bleach per gallon of tap water).
	Use:	For those surfaces that come into contact only with intact skin, e.g., stethoscopes, blood pressure cuffs, splints, etc., and have been visibly contaminated with blood or bloody body fluids. Surfaces must be precleaned of visible material before the germicidal chemical is applied for disinfection.

Table 5. Reprocessing Methods for Equipment Used in the
Prehospital¹ Health-Care Setting – Continued

Low-Level Disinfection:	Destroys:	Most bacteria, some viruses, some fungi, but not <i>Mycobacterium tuberculosis</i> or bacterial spores.
	Methods:	EPA-registered “hospital disinfectants” (no label claim for tuberculocidal activity).
	Use:	These agents are excellent cleaners and can be used for routine housekeeping or removal of soiling in the absence of visible blood contamination.
Environmental Disinfection:		Environmental surfaces which have become soiled should be cleaned and disinfected using any cleaner or disinfectant agent which is intended for environmental use. Such surfaces include floors, woodwork, ambulance seats, countertops, etc.
IMPORTANT:		To assure the effectiveness of any sterilization or disinfection process, equipment and instruments must first be thoroughly cleaned of all visible soil.

¹Defined as setting where delivery of emergency health-care takes place prior to arrival at hospital or other health-care facility.



*Recommendations
and
Reports*

MORBIDITY AND MORTALITY WEEKLY REPORT

Recommendations for Preventing Transmission of Human Immunodeficiency Virus and Hepatitis B Virus to Patients During Exposure-Prone Invasive Procedures

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service
Centers for Disease Control
Atlanta, Georgia 30333



CDC
CENTERS FOR DISEASE CONTROL

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**Recommendations for
Preventing Transmission of Human
Immunodeficiency Virus and
Hepatitis B Virus to Patients During
Exposure-Prone Invasive Procedures**

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Recommendations for Preventing Transmission of Human Immunodeficiency Virus and Hepatitis B Virus to Patients During Exposure-Prone Invasive Procedures

This document has been developed by the Centers for Disease Control (CDC) to update recommendations for prevention of transmission of human immunodeficiency virus (HIV) and hepatitis B virus (HBV) in the health-care setting. Current data suggest that the risk for such transmission from a health-care worker (HCW) to a patient during an invasive procedure is small; a precise assessment of the risk is not yet available. This document contains recommendations to provide guidance for prevention of HIV and HBV transmission during those invasive procedures that are considered exposure-prone.

INTRODUCTION

Recommendations have been made by the Centers for Disease Control (CDC) for the prevention of transmission of the human immunodeficiency virus (HIV) and the hepatitis B virus (HBV) in health-care settings (1-6). These recommendations emphasize adherence to universal precautions that require that blood and other specified body fluids of **all** patients be handled as if they contain blood-borne pathogens (1,2).

Previous guidelines contained precautions to be used during invasive procedures (defined in Appendix) and recommendations for the management of HIV- and HBV-infected health-care workers (HCWs) (1). These guidelines did not include specific recommendations on testing HCWs for HIV or HBV infection, and they did not provide guidance on which invasive procedures may represent increased risk to the patient.

The recommendations outlined in this document are based on the following considerations:

- Infected HCWs who adhere to universal precautions and who do not perform invasive procedures pose no risk for transmitting HIV or HBV to patients.
- Infected HCWs who adhere to universal precautions and who perform certain exposure-prone procedures (see page 4) pose a small risk for transmitting HBV to patients.
- HIV is transmitted much less readily than HBV.

In the interim, until further data are available, additional precautions are prudent to prevent HIV and HBV transmission during procedures that have been linked to HCW-to-patient HBV transmission or that are considered exposure-prone.

BACKGROUND

Infection-Control Practices

Previous recommendations have specified that infection-control programs should incorporate principles of universal precautions (i.e., appropriate use of hand washing, protective barriers, and care in the use and disposal of needles and other sharp instruments) and should maintain these precautions rigorously in all health-care settings (1,2,5). Proper application of these principles will assist in minimizing the risk of transmission of HIV or HBV from patient to HCW, HCW to patient, or patient to patient.

As part of standard infection-control practice, instruments and other reusable equipment used in performing invasive procedures should be appropriately disinfected and sterilized as follows (7):

- Equipment and devices that enter the patient's vascular system or other normally sterile areas of the body should be sterilized before being used for each patient.
- Equipment and devices that touch intact mucous membranes but do not penetrate the patient's body surfaces should be sterilized when possible or undergo high-level disinfection if they cannot be sterilized before being used for each patient.
- Equipment and devices that do not touch the patient or that only touch intact skin of the patient need only be cleaned with a detergent or as indicated by the manufacturer.

Compliance with universal precautions and recommendations for disinfection and sterilization of medical devices should be scrupulously monitored in all health-care settings (1, 7, 8). Training of HCWs in proper infection-control technique should begin in professional and vocational schools and continue as an ongoing process. Institutions should provide all HCWs with appropriate inservice education regarding infection control and safety and should establish procedures for monitoring compliance with infection-control policies.

All HCWs who might be exposed to blood in an occupational setting should receive hepatitis B vaccine, preferably during their period of professional training and before any occupational exposures could occur (8, 9).

Transmission of HBV During Invasive Procedures

Since the introduction of serologic testing for HBV infection in the early 1970s, there have been published reports of 20 clusters in which a total of over 300 patients were infected with HBV in association with treatment by an HBV-infected HCW. In 12 of these clusters, the implicated HCW did not routinely wear gloves; several HCWs also had skin lesions that may have facilitated HBV transmission (10-22). These 12 clusters included nine linked to dentists or oral surgeons and one cluster each linked to a general practitioner, an inhalation therapist, and a cardiopulmonary-bypass-pump technician. The clusters associated with the inhalation therapist and the cardiopulmonary-bypass-pump technician—and some of the other 10 clusters—could possibly have been prevented if current recommendations on universal precautions, including glove use, had been in effect. In the remaining eight clusters, transmission occurred despite glove use by the HCWs; five clusters were linked to obstetricians or gynecologists, and three were linked to cardiovascular surgeons (6, 22-28). In

addition, recent unpublished reports strongly suggest HBV transmission from three surgeons to patients in 1989 and 1990 during colorectal (CDC, unpublished data), abdominal, and cardiothoracic surgery (29).

Seven of the HCWs who were linked to published clusters in the United States were allowed to perform invasive procedures following modification of invasive techniques (e.g., double gloving and restriction of certain high-risk procedures) (6,11-13,15,16, 24). For five HCWs, no further transmission to patients was observed. In two instances involving an obstetrician/gynecologist and an oral surgeon, HBV was transmitted to patients after techniques were modified (6, 12).

Review of the 20 published studies indicates that a combination of risk factors accounted for transmission of HBV from HCWs to patients. Of the HCWs whose hepatitis B e antigen (HBeAg) status was determined (17 of 20), all were HBeAg positive. The presence of HBeAg in serum is associated with higher levels of circulating virus and therefore with greater infectivity of hepatitis-B-surface-antigen (HBsAg)-positive individuals; the risk of HBV transmission to an HCW after a percutaneous exposure to HBeAg-positive blood is approximately 30% (30-32). In addition, each report indicated that the potential existed for contamination of surgical wounds or traumatized tissue, either from a major break in standard infection-control practices (e.g., not wearing gloves during invasive procedures) or from unintentional injury to the infected HCW during invasive procedures (e.g., needle sticks incurred while manipulating needles without being able to see them during suturing).

Most reported clusters in the United States occurred before awareness increased of the risks of transmission of blood-borne pathogens in health-care settings and before emphasis was placed on the use of universal precautions and hepatitis B vaccine among HCWs. The limited number of reports of HBV transmission from HCWs to patients in recent years may reflect the adoption of universal precautions and increased use of HBV vaccine. However, the limited number of recent reports does not preclude the occurrence of undetected or unreported small clusters or individual instances of transmission; routine use of gloves does not prevent most injuries caused by sharp instruments and does not eliminate the potential for exposure of a patient to an HCW's blood and transmission of HBV (6, 22-29).

Transmission of HIV During Invasive Procedures

The risk of HIV transmission to an HCW after percutaneous exposure to HIV-infected blood is considerably lower than the risk of HBV transmission after percutaneous exposure to HBeAg-positive blood (0.3% versus approximately 30%) (33-35). Thus, the risk of transmission of HIV from an infected HCW to a patient during an invasive procedure is likely to be proportionately lower than the risk of HBV transmission from an HBeAg-positive HCW to a patient during the same procedure. As with HBV, the relative infectivity of HIV probably varies among individuals and over time for a single individual. Unlike HBV infection, however, there is currently no readily available laboratory test for increased HIV infectivity.

Investigation of a cluster of HIV infections among patients in the practice of one dentist with acquired immunodeficiency syndrome (AIDS) strongly suggested that HIV was transmitted to five of the approximately 850 patients evaluated through June 1991 (36-38). The investigation indicates that HIV transmission occurred during dental care, although the precise mechanisms of transmission have not been determined. In two other studies, when patients cared for by a general surgeon and a surgical

resident who had AIDS were tested, all patients tested, 75 and 62, respectively, were negative for HIV infection (39, 40). In a fourth study, 143 patients who had been treated by a dental student with HIV infection and were later tested were all negative for HIV infection (41). In another investigation, HIV antibody testing was offered to all patients whose surgical procedures had been performed by a general surgeon within 7 years before the surgeon's diagnosis of AIDS; the date at which the surgeon became infected with HIV is unknown (42). Of 1,340 surgical patients contacted, 616 (46%) were tested for HIV. One patient, a known intravenous drug user, was HIV positive when tested but may already have been infected at the time of surgery. HIV test results for the 615 other surgical patients were negative (95% confidence interval for risk of transmission per operation = 0.0%-0.5%).

The limited number of participants and the differences in procedures associated with these five investigations limit the ability to generalize from them and to define precisely the risk of HIV transmission from HIV-infected HCWs to patients. A precise estimate of the risk of HIV transmission from infected HCWs to patients can be determined only after careful evaluation of a substantially larger number of patients whose exposure-prone procedures have been performed by HIV-infected HCWs.

Exposure-Prone Procedures

Despite adherence to the principles of universal precautions, certain invasive surgical and dental procedures have been implicated in the transmission of HBV from infected HCWs to patients, and should be considered exposure-prone. Reported examples include certain oral, cardiothoracic, colorectal (CDC, unpublished data), and obstetric/gynecologic procedures (6, 12, 22-29).

Certain other invasive procedures should also be considered exposure-prone. In a prospective study CDC conducted in four hospitals, one or more percutaneous injuries occurred among surgical personnel during 96 (6.9%) of 1,382 operative procedures on the general surgery, gynecology, orthopedic, cardiac, and trauma services (43). Percutaneous exposure of the patient to the HCW's blood may have occurred when the sharp object causing the injury recontacted the patient's open wound in 28 (32%) of the 88 observed injuries to surgeons (range among surgical specialties = 8%-57%; range among hospitals = 24%-42%).

Characteristics of exposure-prone procedures include digital palpation of a needle tip in a body cavity or the simultaneous presence of the HCW's fingers and a needle or other sharp instrument or object in a poorly visualized or highly confined anatomic site. Performance of exposure-prone procedures presents a recognized risk of percutaneous injury to the HCW, and—if such an injury occurs—the HCW's blood is likely to contact the patient's body cavity, subcutaneous tissues, and/or mucous membranes.

Experience with HBV indicates that invasive procedures that do not have the above characteristics would be expected to pose substantially lower risk, if any, of transmission of HIV and other blood-borne pathogens from an infected HCW to patients.

RECOMMENDATIONS

Investigations of HIV and HBV transmission from HCWs to patients indicate that, when HCWs adhere to recommended infection-control procedures, the risk of transmitting HBV from an infected HCW to a patient is small, and the risk of transmitting HIV is likely to be even smaller. However, the likelihood of exposure of the patient to an HCW's blood is greater for certain procedures designated as exposure-prone. To minimize the risk of HIV or HBV transmission, the following measures are recommended:

- All HCWs should adhere to universal precautions, including the appropriate use of hand washing, protective barriers, and care in the use and disposal of needles and other sharp instruments. HCWs who have exudative lesions or weeping dermatitis should refrain from all direct patient care and from handling patient-care equipment and devices used in performing invasive procedures until the condition resolves. HCWs should also comply with current guidelines for disinfection and sterilization of reusable devices used in invasive procedures.
- Currently available data provide no basis for recommendations to restrict the practice of HCWs infected with HIV or HBV who perform invasive procedures not identified as exposure-prone, provided the infected HCWs practice recommended surgical or dental technique and comply with universal precautions and current recommendations for sterilization/disinfection.
- Exposure-prone procedures should be identified by medical/surgical/dental organizations and institutions at which the procedures are performed.
- HCWs who perform exposure-prone procedures should know their HIV antibody status. HCWs who perform exposure-prone procedures and who do not have serologic evidence of immunity to HBV from vaccination or from previous infection should know their HBsAg status and, if that is positive, should also know their HBeAg status.
- HCWs who are infected with HIV or HBV (and are HBeAg positive) should not perform exposure-prone procedures unless they have sought counsel from an expert review panel and been advised under what circumstances, if any, they may continue to perform these procedures.* Such circumstances would include notifying prospective patients of the HCW's seropositivity before they undergo exposure-prone invasive procedures.

*The review panel should include experts who represent a balanced perspective. Such experts might include all of the following: a) the HCW's personal physician(s), b) an infectious disease specialist with expertise in the epidemiology of HIV and HBV transmission, c) a health professional with expertise in the procedures performed by the HCW, and d) state or local public health official(s). If the HCW's practice is institutionally based, the expert review panel might also include a member of the infection-control committee, preferably a hospital epidemiologist. HCWs who perform exposure-prone procedures outside the hospital/institutional setting should seek advice from appropriate state and local public health officials regarding the review process. Panels must recognize the importance of confidentiality and the privacy rights of infected HCWs.

- **Mandatory testing of HCWs for HIV antibody, HBsAg, or HBeAg is not recommended. The current assessment of the risk that infected HCWs will transmit HIV or HBV to patients during exposure-prone procedures does not support the diversion of resources that would be required to implement mandatory testing programs. Compliance by HCWs with recommendations can be increased through education, training, and appropriate confidentiality safeguards.**

HCWS WHOSE PRACTICES ARE MODIFIED BECAUSE OF HIV OR HBV STATUS

HCWs whose practices are modified because of their HIV or HBV infection status should, whenever possible, be provided opportunities to continue appropriate patient-care activities. Career counseling and job retraining should be encouraged to promote the continued use of the HCW's talents, knowledge, and skills. HCWs whose practices are modified because of HBV infection should be reevaluated periodically to determine whether their HBeAg status changes due to resolution of infection or as a result of treatment (44).

NOTIFICATION OF PATIENTS AND FOLLOW-UP STUDIES

The public health benefit of notification of patients who have had exposure-prone procedures performed by HCWs infected with HIV or positive for HBeAg should be considered on a case-by-case basis, taking into consideration an assessment of specific risks, confidentiality issues, and available resources. Carefully designed and implemented follow-up studies are necessary to determine more precisely the risk of transmission during such procedures. Decisions regarding notification and follow-up studies should be made in consultation with state and local public health officials.

ADDITIONAL NEEDS

- Clearer definition of the nature, frequency, and circumstances of blood contact between patients and HCWs during invasive procedures.
- Development and evaluation of new devices, protective barriers, and techniques that may prevent such blood contact without adversely affecting the quality of patient care.
- More information on the potential for HIV and HBV transmission through contaminated instruments.
- Improvements in sterilization and disinfection techniques for certain reusable equipment and devices.
- Identification of factors that may influence the likelihood of HIV or HBV transmission after exposure to HIV- or HBV-infected blood.

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APPENDIX

Definition of Invasive Procedure

An invasive procedure is defined as "surgical entry into tissues, cavities, or organs or repair of major traumatic injuries" associated with any of the following: "1) an operating or delivery room, emergency department, or outpatient setting, including both physicians' and dentists' offices; 2) cardiac catheterization and angiographic procedures; 3) a vaginal or cesarean delivery or other invasive obstetric procedure during which bleeding may occur; or 4) the manipulation, cutting, or removal of any oral or perioral tissues, including tooth structure, during which bleeding occurs or the potential for bleeding exists."

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U.S. Department of Labor

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MAR 26 1992

The Honorable Ron Wyden
Chairman
Subcommittee on Regulation,
Business Opportunities, and Energy
Committee on Small Business
U.S. House of Representatives
Washington, D.C. 20515

Dear Chairman Wyden:

Thank you for your letter of February 12, addressed to Charles E. Adkins, Director of Health Standards Programs, thanking him for his recent testimony before your subcommittee on the subject of protecting healthcare employees from needlestick injuries. You also requested the Occupational Safety and Health Administration (OSHA) to provide you with additional information either confirming or rejecting the assertion made during the hearing that needlesticks have surpassed back injuries as the most serious workers compensation injury in hospitals.

Comprehensive statistics on the nature and source of occupational injuries are not readily available. The Bureau of Labor Statistics is in the process of redesigning the Occupational Safety and Health statistical system. When that system is in place and operating, it may be possible to answer these types of questions with greater accuracy.

In the absence of comprehensive statistics, an alternative is to contact individual State Workers' Compensation Agencies. While we did not contact every workers' compensation plan in the country, we were able to obtain some data from the Oregon Department of Insurance and Finance. They searched their records for disabling injuries (as defined by the State of Oregon) occurring in hospitals during the years 1987 to 1992. This search revealed 5 needlestick injuries resulting in disability, and over 2,700 back strains and sprains that resulted in disability. Of course, the experience of Oregon may not reflect conditions nationwide, if for no other reason than the variation in workers' compensation policies.

-2-

Needlestick injuries are very serious events. They have the potential for very serious consequences, including disability. However, at the present time, in hospitals, it does not appear as though these injuries result in disabling workers' compensation claims as frequently as back injuries.

We hope we have been of assistance.

Sincerely,

A handwritten signature in cursive script that reads "Dorothy L. Strunk". The signature is written in dark ink and is positioned above the typed name.

Dorothy L. Strunk
Acting Assistant Secretary

UNIVERSITY OF VIRGINIA

HEALTH
SCIENCES
CENTERDEPARTMENT OF
NEUROLOGICAL SURGERY

February 14, 1992

James S. Benson
 Director of the Center for Devices and Radiological Health
 Food and Drug Administration
 12720 Twinbrook Parkway
 Rockville, MD 20857

Dear Mr. Benson:

I would like to draw your attention to a serious and unnecessary hazard in the health care workplace resulting from the inappropriate adaptation of a common medical device for an unintended purpose. I also request that the Food and Drug Administration issue a Medical Alert to advise health care institutions against the inappropriate use of this device, and to make recommendations on appropriate alternatives.

The device is the hypodermic needle which is sometimes inappropriately used for non-hypodermic purposes, specifically, as a connection between two pieces of intravenous equipment. The terms "piggyback" or "intermittent I.V." are commonly associated with this equipment configuration. It consists of an exposed hypodermic needle attached to the intravenous tubing on a secondary medication set. The hypodermic needle is inserted either into a connecting "Y" site on a primary intravenous line ("piggyback"), or directly into the intravenous access port connected to the patient's intravenous catheter ("intermittent I.V."). The use of the hypodermic needle for "piggyback" and "intermittent I.V." connections results in hazards to both health care workers and to patients. The hazards include:

1. *Needlestick injuries and the transmission of bloodborne pathogens to health care workers.* Research has shown that intravenous tubing/needle assemblies have a higher risk of needlestick injury than any other needle devices; needlestick rates more than six times as high as those from disposable syringes have been documented.¹ Furthermore, needlesticks from intravenous tubing/needle assemblies account for a large proportion of needlesticks from hollow-bore needles. One quarter of all needlesticks in one hospital study were caused by intravenous tubing/needle assemblies alone.² A recent confirmation of this figure was obtained from the New York State trial of needlestick protective devices. In hospitals where needleless or shielded needle intravenous line connectors replaced the conventional hypodermic needle connection, hospital needlestick reports dropped between 21% to 29%.²

Bloodborne pathogens are needlessly transmitted to health care workers by intravenous tubing/needle assemblies. The well-documented case of Jane Doe, a nurse at San Francisco General Hospital, is a tragic example of HIV transmission following a

needlestick from a hypodermic needle used for an intermittent I.V.³ Another similar instance has recently been reported to the Centers for Disease Control. The potential for transmission of other bloodborne pathogens such as hepatitis B exists as well. Furthermore, needles on intravenous lines often cause needlesticks when they protrude from disposal containers. When it cannot be determined how the needle was originally used, a health care worker must endure the full needlestick follow-up protocol including the uncertainty of waiting for the results of HIV tests for up to twelve months.

The cost of following-up these preventable needlesticks is considerable. With an estimated 800,000 needlesticks occurring each year, 200,000 of which are likely to be caused by intravenous tubing/needle assemblies, at a cost of \$400 per needlestick (not considering the cost of disease) an estimated \$80,000,000 in unnecessary cost is incurred by the inappropriate use of hypodermic needles.^{4,5}

2. *The inadvertent disconnection of "piggyback" or "intermittent I.V." needles.* Hypodermic needles do not provide a secure connection with latex intravenous ports. The friction between the steel needle and the latex port is insufficient to assure a reliable connection. To overcome this problem, it is common practice to employ the makeshift solution of securing the junction with surgical tape. Despite the surgical tape, these intravenous line connections frequently fail, resulting in the unintended interruption of intravenous therapy. Furthermore, health care workers sustain needlesticks from exposed needles dangling from unintentionally disconnected secondary medication sets.¹

3. *Hypodermic needles breaking off inside intravenous access ports, and migrating through the intravenous tubing and potentially into the patients' bloodstream.* Because there is no feature on a hypodermic needle to stabilize and secure its connection to an intravenous port, there remains considerable "play" in the connection which allows the needle to rock or wobble laterally with the latex septum acting as a fulcrum. The rocking movement can cause the needle to bend repeatedly near its connection to the needle hub, and occasionally needles break off inside intravenous ports. This is more likely to occur with small gauge needles. Between November 1, 1988 and May 22, 1990, six reports were filed with the FDA's Device Experience Network describing hypodermic needles breaking off inside intravenous access ports. Two of the reports refer to multiple incidents.

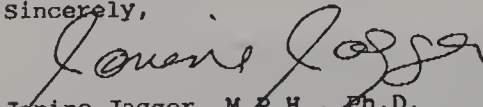
When needles are connected to intravenous catheter injection sites (close to the patient rather than "upstream"), there is the potential for needles to break off and travel through the lumen of the catheter directly into the patient's bloodstream.

More than a dozen alternative devices are currently available that were specifically designed for the purpose of accessing or connecting to intravenous ports. A list of available alternatives is attached. Some of the devices eliminate the risk of needlesticks by eliminating the needle altogether. Some substantially reduce the risk of needlesticks by providing a large gauge needle that is recessed behind a fixed shield. The devices

provide a stable junction that prevents wobbling movement, or a mechanism for securely grasping the intravenous access port to avoid inadvertent disconnection. Other available alternatives include stopcocks and luer lock fittings that have been available for decades. They are made by a variety of companies.

European countries never adopted the American practice of using hypodermic needles for accessing intravenous ports. Consequently, we must now attempt to eliminate risks that need never have existed. Many hospitals are already converting to needleless or shielded needle intravenous equipment. A **Medical Alert** issued by the Food and Drug Administration could speed the process of transition and reduce risk to both health care workers and patients in a more timely manner. I will be pleased to assist the FDA in drafting and/or disseminating a Medical Alert on this crucial issue.

Sincerely,



Janine Jagger, M.P.H., Ph.D.
Associate Professor of Neurosurgery

enclosures: list of alternative products
list of FDA Device Experience Network reports

REFERENCES

¹ Jagger J, Hunt EH, Brand-Elnaggar J, Pearson RD. Rates of needle-stick injury caused by various devices in a university hospital. *New Engl Jrnl Med* 1988; 319:284-288.

² Chiarello L. Testimony on needlestick prevention technology. Presented before U.S. Congress Committee on Small Business, Subcommittee on Regulation, Business Opportunities, and Energy. Washington, D.C., February 7, 1992.

³ Testimony of Jane Doe before the Occupational Safety and Health Administration hearing on the proposed rule on the Occupational Exposure to Bloodborne Pathogens. San Francisco, January 16, 1990.

⁴ Jagger J., Pearson RD. Universal Precautions: Still missing the point on needlesticks. *Infect Control Hosp Epidemiol* 1991;12:211-213.

⁵ Jagger J, Hunt EH, Pearson RD. Estimated cost of needlestick injuries for six major needle devices. *Infect Control Hosp Epidemiol* 1990;11:584-588

FDA Device Experience Network

Reports Of Hypodermic Needles Breaking Off Inside Intravenous Ports

PAP N4477 11/01/88 MONJECT NEEDLE, 20 GAUGE, 1 INCH SHERWOOD MEDICAL CO.
 REPT TYPE: DEVICE EXPERIENCE NETWORK CATALOG NO: NOT SUBMITTED
 MODEL NO: 25D131
 FINAL DESCRIPTION:
 RPTR HAD TWO INCIDENTS INVOLVING THE NEEDLE. BOTH INCIDENTS WERE BASICALLY THE SAME IN WHICH THE NEEDLE BROKE OFF THE CENTRAL LINES. THE CO HAD SINCE CHANGED THE EPXY, BUT AS FAR AS THE RPTR KNOWS THERE HAS BEEN NO RECALL. HE FEELS THAT THERE SHOULD BE A RECALL. ALSO, THREE MONTHS AGO THE NEEDLE GUARD WAS CHANGED. THE PLASTIC IS THINNER AND SMALLER IN DIAMETER THAN THE OLD GUARD WHICH INCREASES THE CHANCE OF STICKS. SINCE THE CHANGE THERE HAVE BEEN A DOZEN STICKS THROUGH THE CAP. NEEDLES FROM THE ABOVE LOT AND OTHERS WERE AFFECTED. RPTR IS HOLDING SAMPLE.
 CLOSEOUT DESCRIPTION: THE CAUSE OF THIS EVENT HAS NOT BEEN DETERMINED. IN ADDITION, AVAILABLE FREQUENCY AND SEVERITY DATA DO NOT INDICATE THAT ANY FURTHER INVESTIGATION IS NECESSARY AT THIS TIME. BOTH THE FREQUENCY AND SEVERITY OF THIS EVENT WILL BE PERIODICALLY MONITORED TO DETERMINE IF ANY FOLLOW-UP AND/OR OTHER ACTION IS INDICATED.

PAP N48487 11/07/88 MONJECT 250 NEEDLES, 22 GAUGE SHERWOOD MEDICAL CO.
 REPORT TYPE: DEVICE EXPERIENCE NETWORK CATALOG NO: NOT SUBMITTED
 MODEL NO: NOT SUBMITTED
 FINAL DESCRIPTION:
 THE NEEDLE USED TO HAVE AN ALUMINUM HUB WHICH WAS CHANGED TO AN EPOXY HUB. WITH THIS HUB NEEDLES FELL OFF, SOMETIMES IN CENTRAL LINES. THE CO HAS SINCE CHANGED THE EPOXY, BUT AS FAR AS THE RPTR KNOWS THERE HAS BEEN NO RECALL. HE FEELS THAT THERE SHOULD BE A RECALL. ALSO, THREE MONTHS AGO THE NEEDLE GUARD WAS CHANGED. THE PLASTIC IS THINNER AND SMALLER IN DIAMETER THAN THE OLD GUARD WHICH INCREASES THE CHANCE OF STICKS. SINCE THE CHANGE THERE HAVE BEEN A DOZEN STICKS THROUGH THE CAP. NEEDLES FROM THE ABOVE LOT AND OTHERS WERE AFFECTED. RPTR IS HOLDING SAMPLE.
 CLOSEOUT DESCRIPTION: THE CAUSE OF THIS EVENT HAS NOT BEEN DETERMINED. IN ADDITION, AVAILABLE FREQUENCY AND SEVERITY DATA DO NOT INDICATE THAT ANY FURTHER INVESTIGATION IS NECESSARY AT THIS TIME. BOTH THE FREQUENCY AND SEVERITY OF THIS EVENT WILL BE PERIODICALLY MONITORED TO DETERMINE IF ANY FOLLOW-UP AND/OR OTHER ACTION IS INDICATED.

PAP N49090 04/24/89 IN NEEDLE, 23 GAUGE, 1 INCH BECTON-DICKINSON & CO.
 REPORT TYPE: DEVICE EXPERIENCE NETWORK CATALOG NO: NOT SUBMITTED
 MODEL NO: NOT SUBMITTED
 FINAL DESCRIPTION:
 THE METAL NEEDLE BROKE OFF AT THE PLASTIC HUB AND STARTED TO TRAVEL THROUGH THE IV TUBING. THE SET WAS DISCONNECTED FROM THE PT. RPTR IS HOLDING SAMPLE.
 CLOSEOUT DESCRIPTION: THE CAUSE OF THIS EVENT HAS NOT BEEN DETERMINED. HOWEVER, THE INFORMATION IN THIS REPORT AND/OR ITS FOLLOW-UP SUGGESTS THAT THE EVENT MAY HAVE BEEN CAUSED BY THE USE OF THE DEVICE. BOTH THE FREQUENCY AND SEVERITY OF THIS EVENT WILL BE PERIODICALLY MONITORED TO DETERMINE IF ANY FOLLOW-UP AND/OR OTHER ACTION IS INDICATED.

PAP N50096 12/21/89 MONOJECT NEEDLE, 22 GA SHERWOOD MEDICAL
 REPORT TYPE: DEVICE EXPERIENCE NETWORK CATALOG NO: NOT SUBMITTED
 MODEL NO: NOT SUBMITTED
 FINAL DESCRIPTION:
 THE RPTR HAS USED THESE PRODUCTS FOR 20 YRS. THIS PAST SUMMER THERE WERE NEEDLE BREAKAGES IN SECONDARY IV PORTS; THE NEEDLES WERE ABLE TO BE RETRIEVED WITH HEMOSTATS. THE CO INVESTIGATED THE BREAKAGES. IN THE PAST MONTH, THERE HAVE BEEN TWO ADD'L BREAKAGES. THE CO TOLD THE RPTR THAT THIS HOSP IS THE ONLY ONE WITH THIS PROBLEM.
 CLOSEOUT DESCRIPTION: THE CAUSE OF THIS EVENT HAS NOT BEEN DETERMINED. IN ADDITION, AVAILABLE FREQUENCY AND SEVERITY DATA DO NOT INDICATE THAT ANY FURTHER INVESTIGATION IS NECESSARY AT THIS TIME. BOTH THE FREQUENCY AND SEVERITY OF THIS EVENT WILL BE PERIODICALLY MONITORED TO DETERMINE IF ANY FOLLOW-UP AND/OR OTHER ACTION IS INDICATED.

PAP N50779 05/22/90 PRECISION GLIDE NEEDLE, 19 G BECTON-DICKINSON
 REPORT TYPE: DEVICE EXPERIENCE NETWORK CATALOG NO: 5186
 MODEL NO: NOT SUBMITTED
 FINAL DESCRIPTION:
 1) HUB SEPARATED FROM NEEDLE BARREL. NEEDLE BARREL REMAINED IN SECONDARY PORT SITE OF IV TUBING. THIS HAPPENED WHEN A PT. ATTEMPTED TO REMOVE THE NEEDLE FROM THE SECONDARY PORT SITE AFTER INFUSION OF BLOOD INTO A PT. UNABLE TO DETERMINE IF HUB AND BARREL SEPARATED DUE TO FAULTY ASSEMBLY OR 2) HUB BROKE OFF FROM BARREL. PRODUCT SENT TO MFR, ON 1/16/90.

PAP N50779 05/22/90 PRECISION GLIDE NEEDLE, 1 INCH BECTON-DICKINSON & CO.
 REPORT TYPE: DEVICE EXPERIENCE NETWORK CATALOG NO: 5177
 MODEL NO: NOT SUBMITTED
 FINAL DESCRIPTION:
 BROKEN OR BENT AT HUB IN IV PART. IV PIGGYBACKED INTO IV OR HEPARIN LOCK, NO LOT NUMBER AVAILABLE, NO HARM TO PTS. ADD'L EVENT DATES: 5/11, 5/14/ AND 5/16. RPTR IS HOLDING SAMPLE.
 CLOSEOUT DESCRIPTION: THE CAUSE OF THIS EVENT HAS NOT BEEN DETERMINED. HOWEVER, THE INFORMATION IN THIS REPORT AND/OR ITS FOLLOW-UP SUGGESTS THAT THE EVENT MAY HAVE BEEN CAUSED BY THE USE OF THE DEVICE. BOTH THE FREQUENCY AND SEVERITY OF THIS EVENT WILL BE PERIODICALLY MONITORED TO DETERMINE IF ANY FOLLOW-UP AND/OR OTHER ACTION IS INDICATED.

I.V. Tubing/Needle Assembly Safety Devices

1. **SAFSITE Needle-free IV Access System**,
Burron Medical, Inc. (B.Braun of America Company), Bethlehem, PA
(800) 523-9695
2. **Centurion Kleen-Needle System**
Tri-State Hospital Supply Corporation, Howell, MI
(800) 248-4058
3. **IMS Stick-Gard Safety Needle**
International Medication Systems, Limited (IMS), South El Monte, CA
(800) 423-4136
4. **Baxter Protective Needle-Lock**
Baxter Healthcare Corporation, Deerfield, IL
(708) 940-5743
5. **Baxter Interlink IV Access System**
Baxter Healthcare Corporation, Deerfield, IL
(708) 940-5743
6. **ICU Medical Click-Lock**
ICU Medical, Inc., Mission Viejo, CA
(800) 824-7890
7. **SPIVE (Special Purpose IV-Entering)**
Pascall Medical Corporation, Melbourne, FL
(407) 242-9603
8. **NeedlePoint Guard IV "Piggyback" Infusion Set**
NeedlePoint Guard, Inc., Grand Island, NE
(800) 635-5878
9. **McGaw Protected Needle**
Kendall McGaw Laboratories, Inc., Irvine, CA
(714) 660-2000
10. **Safeport Injection Site**
L&W Technology, Inc., Los Angeles, CA
(800) 648-5920; in CA (213) 275-7464
11. **Ryan Medical Saf-T Klik IV In-line Connector**
Ryan Medical Inc., Brentwood, TN
(615) 370-4242
12. **In-line stopcocks**
13. **Luer fittings**

U.S. Department of Labor

Assistant Secretary for
Occupational Safety and Health
Washington, D.C. 20210

FEB 19 1992

The Honorable Ron Wyden
Chairman
Subcommittee on Regulation,
Business Opportunities, and Energy
Committee on Small Business
U.S. House of Representatives
Washington, D.C. 20515

Dear Chairman Wyden:

Thank you for your letter of December 18, 1991, concerning the final standard for Occupational Exposure to Bloodborne Pathogens. In your letter, you asked a number of questions about the standard as it relates to needlesticks. We have provided answers to each of the questions outlined in your letter.

Question 1: The OSHA guidelines require employers to provide workers with additional training, protective clothing, and puncture-proof receptacles for contaminated needles and other medical wastes, as well as, in the case of hepatitis, vaccination against the virus. Is it OSHA's contention that these regulations contribute significantly to decreasing needlestick injuries among health care workers?

Answer: Some of these provisions, such as training and needle disposal containers, contribute to the reduction in needlesticks. Other provisions, such as the hepatitis B vaccine, reduce the likelihood of infection if an exposure incident, such as a needlestick or a blood splash to the eyes, occurs.

Question 2: The use of unnecessary needles -- needles not intended for injection purposes, i.e., IV connectors which expose the health care worker to an unnecessary risk of a needlestick-- contributes greatly to the transmission of bloodborne pathogens among hospital and health care workers. The subcommittee has been told that such needles can be eliminated altogether or replaced with safer preventive needle technology. Would OSHA agree with this assessment?

Answer: The final standard does require the hierarchy of controls, that is, engineering and work practice controls in preference to personal protective clothing and equipment. Therefore, employers are responsible for evaluating new, safer equipment as it becomes available. However, the Agency has not made a final determination that employers may use only IV connectors that do not use needles.

Question 3: The OSHA guidelines do not address the topic of safer needle technologies as a possible method for curtailing the spread of blood-borne disease among hospital and health care workers. What reasons can OSHA give for this omission? Is it OSHA's view that such technology would not significantly reduce transmission of infectious disease?

Answer: As stated above, the final standard relies on the use of engineering controls. Safer needle technology is one example of an engineering control. Paragraph (b) Definitions of the final standard mentions new needle design as an example of an engineering control.

Engineering Controls means controls (e.g. sharps disposal containers, self-sheathing needles) that isolate or remove the bloodborne pathogens hazard from the workplace.

The Agency does not certify particular devices and therefore we did not recommend the use of specific devices. However, we certainly recognize the importance of the new equipment.

Question 4: It is commonly said in the health care community that needlestick injuries are caused by the carelessness of health care workers or their lack of compliance with universal precautions. In OSHA's view, is this an accurate assessment of the cause of most needlestick injuries?

Answer: The agency received a considerable number of comments on the needlestick issue. It is clear that both training in the proper handling and disposal of sharps, and safer equipment are important in reducing needlestick injuries.

Question 5: In terms of enforcement, what steps is OSHA taking to ensure that these standards are successfully implemented?

Answer: OSHA will enforce the Bloodborne Pathogens Standard in the same manner that it enforces other standards. All OSHA inspections will include a review of the employer's Exposure Control Plan, if appropriate, and the inspection will be expanded to all areas involving occupational exposure to blood and other potentially infectious materials if the review of the Plan shows significant deficiencies.

The agency is currently drafting a Compliance Directive to establish uniform inspection procedures and guidelines to be followed by OSHA field offices when conducting inspections and issuing citations. OSHA compliance staff will be thoroughly trained in the requirements of the standard.

To ensure that employers are aware of and implement the new regulation, OSHA has established a Bloodborne Pathogens Outreach Task Force to coordinate various agency efforts to inform the regulated community about the standard and its requirements.

The outreach program will include, among other things, the publication of a series of fact sheets highlighting individual requirements of the standard; a generic booklet outlining the provisions of the regulation; several specialized booklets targeted for Acute Care Facilities, Dental Offices, Emergency Responders, and Long Term Healthcare Facilities; videotapes and a slide presentation explaining the standard; short articles in the Job Safety and Health Quarterly magazine published by OSHA; outreach packages prepared by OSHA's Training Institute; notification by letter to professional associations, unions, and employee organizations to alert them to the requirements of the standard; notification by letter to Federal Agency safety and health officials of the new standard to enable them to protect Federal employees; letters to governors of states without Federally-approved State Plan Programs to encourage them to extend the protection of the standard to public sector employees; and in August 1992, OSHA is co-sponsoring a National Conference with the Centers for Disease Control and the Food and Drug Administration that will focus attention on sharps injuries and performance safety of medical devices and instruments.

Question 6: The OSHA guidelines call for specific engineering controls such as puncture-resistant containers for used needles. Is this the extent to which OSHA has considered safer technology or are there other provisions addressing the issue of safer needlestick prevention technologies?

Answer: Please see the answer for question 3.

Question 7: The subcommittee has also been told that the average cost of diagnosing a hospital or health care worker infected with hepatitis B or HIV as a result of a needlestick is around \$400 per injury.

First, how accurate are these estimates? Second, has OSHA done a cost/benefit analysis to determine which cost is greater -- implementing the new standard or diagnosing and treating needlestick due to unsafe needle devices in the hospital and health care workplace?

Answer: The figures you have quoted for the total annual costs of the Bloodborne Pathogens Standard represent OSHA's preliminary estimates. These numbers have now been finalized, so that the

total annual costs of the standard amounts to about \$813 million for all affected industries. The largest annual costs are for personal protective equipment such as gloves (\$327 million).

The cost of post-exposure evaluation and follow-up would depend on a number of factors, such as whether the employee had been previously vaccinated against hepatitis B, whether it was necessary to administer hepatitis B immune globulin, and whether the employee was infected with either HIV or HBV at the time of the exposure incident. We did not calculate the cost per employee but rather per industrial segment. However, the figure of \$400 seems reasonable, particularly if vaccine and/or hepatitis B immune globulin is necessary. The Agency did not perform a cost-benefit analysis to compare diagnosis of illness and prevention of needlestick.

Question 8: What are your plans for enforcing Section (d)(2)(i)? What are your plans for training compliance officers and what do you consider to be a feasible abatement program?

Answer: Paragraph (d)(2)(i) shall be cited if engineering and work practice controls are not used, where such controls could eliminate or minimize the exposure. OSHA will encourage employers to institute a mechanism to evaluate the efficacy of existing controls and to review the feasibility of new engineering technology. For example, the employer may adopt a more advanced control as existing supplies are depleted. We have also prepared a Compliance Directive to provide additional guidance for our Compliance Officers. It is not possible to define a generic abatement plan. The contents of the plan would depend on the circumstances.

OSHA's Training Institute will conduct a Train-the-Trainer seminar on the Bloodborne Pathogens standard February 19-20 for persons representing Federal State OSHA personnel and State consultation personnel. The seminar participants will in turn train other Federal and State Compliance Officers and State Consultants.

In addition, all OSHA Field offices, State Designees, and State consultation agencies have received three videotapes, produced by the American Hospital Association, for use in training in-house staff on Universal Precautions procedures and needlestick prevention. OSHA will also be developing and distributing a videotape on various aspects of the standard, which will be used for training.

Furthermore, OSHA is preparing a series of fact sheets highlighting individual requirements of the standard, which will cover topics such as hepatitis B vaccination, use of sharps, personal protective equipment, exposure incidents, and medical procedures.

Question 9: Please send us information about any hospitals or other institutions which use safer medical devices which meet the requirements of the standard and which you considered to be a model program. Also, please include any information that you may have on the institution's comparative costs of implementing the standard.


Answer: OSHA received approximately 3,000 comments and heard testimony from more than 400 witnesses during the public hearings. Although many commenters expressed their belief that OSHA should require the use of engineering controls in the final standard, no commenter presented OSHA with a model program.

Question 10: OSHA is a co-sponsor of a conference on safer medical devices scheduled for August 1992. Why did OSHA decide to co-sponsor this conference and what will be your role?

Answer: The three sponsoring agencies, the Occupational Safety and Health Administration (OSHA), the Centers for Disease Control (CDC), and the Food and Drug Administration (FDA), have all recognized the important role that contaminated sharps play in the transmission of bloodborne diseases in the workplace. For that reason, staff of all three agencies met early in 1991 to discuss the possibility of sponsoring a national conference on the prevention of device-mediated bloodborne infections. OSHA is an active partner with the FDA and the CDC, contributing \$50,000 and considerable staff time to make the August 17-19, 1992 conference a success.

Thank you for your interest in this matter. We hope that we have answered your questions satisfactorily and provided you with adequate information to assist you in your investigation. If you have any further questions on this matter, Dr. Susan Harwood, Director, Office of Risk Assessment will be glad to assist you. She can be reached by telephone at (202) 523-7157.

Sincerely,


Dorothy L. Strunk
Acting Assistant Secretary



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

FEB 4 1992

The Honorable Ron Wyden
Chairman, Subcommittee on Regulation,
Business Opportunities and Energy
Committee on Small Business
House of Representatives
Washington, D.C. 20515-6318

Dear Mr. Wyden:

This is in response to your letter of December 20, 1991, requesting information on emerging needle technologies and the dangers posed to healthcare workers from needlesticks. The following answers correspond to your questions as posed:

Question: What are the major regulatory, structural or procedural roadblocks that have prevented small and large manufacturers from successfully marketing and deploying safer needle technology in hospitals and healthcare centers?

Answer

From a regulatory perspective, all medical devices are subject to Food and Drug Administration (FDA) premarket clearance. Needles and syringes are Class II medical devices, which means that they are subject to the "general controls" of the Federal Food, Drug, and Cosmetic Act, as well as "special controls" recently created by the Safe Medical Devices Act of 1990. Procedurally, because of these requirements, a manufacturer who wants to introduce a new needle or syringe to the market must submit a premarket notification (510(k)) to FDA at least 90 days prior to the planned introduction date. FDA must find the new device to be substantially equivalent to a legally marketed device and notify the applicant in writing of that finding before the new device can be marketed. The applicant must comply with the other requirements under the Act as well, including registration and listing, good manufacturing practices, etc.

The evaluation of the 510(k) includes a comparison of descriptive data and, in many cases, performance data of the new device to the legally marketed device. In addition, there are pending domestic and international industry standards for these devices that FDA considers in its evaluation.

Page 2 - The Honorable Ron Wyden

In sum, these considerations ensure that the new devices are as safe and effective as the legally marketed predicate devices. The review process is generally routine and expeditious for these types of devices.

Question: What are the factors that may inhibit the development and commercialization of safer needle technologies? Are the large manufacturers, such as Sherwood and Becton-Dickinson supportive of this type of technology? We are particularly interested in the prospects this technology has for small manufacturers. Do they have a place in the marketing and implementation of safer needle technology in hospitals and healthcare facilities?

Answer Factors (internal and external) that inhibit development and commercialization of safer needle technologies are many, most of which are not related to regulation. They include, for example:

- availability and cost of capital
- design and testing capabilities of the developer
- regulatory/legal/business expertise of the developer
- marketing acumen
- competition
- user interest and acceptance of the new device
- the overall business environment
- the available market niche.

Small companies and entrepreneurs are a significant portion of 510(k) applicants. In general, small manufacturers make up the large majority of device manufacturers. The small manufacturer is up against the forces that impede introduction of any product.

Question: What are the five most pressing issues facing healthcare worker safety regarding needlestick injuries?

Answer The Occupational Safety and Health Administration (OSHA) and the Centers for Disease Control (CDC) has more complete information regarding healthcare worker safety issues. OSHA recently published a new healthcare worker safety regulation, which includes anti-needlestick issues (56 FR 64003, December 6, 1991).

Page 3 - The Honorable Ron Wyden

Question: In terms of cost, do you know of any on-going studies currently evaluating the cost-benefit of deploying this new safer technology? If so, have the results been positive or does there need to be a more indepth look at the advantage this technology might have for preventing HIV transmission among healthcare workers?

Answer The potential cost-benefit of new needle and syringe technology is not a primary consideration of FDA in its evaluation of medical devices. However, FDA is aware of some published information on this subject. For example, a publication by ECRI, May 1991, Vol. 20, No. 5, discusses costs of needlestick prevention devices.

Question: The use of unnecessary needles -- needles not intended for injection purposes, i.e. IV connectors which expose the healthcare worker to an unnecessary risk of a needlestick-- contributes greatly to the transmission of blood-borne pathogens among hospital and healthcare workers. The subcommittee has been told that such needles can be eliminated altogether or replaced with safer preventive needle technology. Would FDA agree with this assessment?

Answer FDA would agree that it is within the realm of advancing technology to create devices that afford less chance of incurring a needlestick. Devices have already been cleared by FDA that address the specific problem mentioned (IV connectors). While minimizing needlesticks is important to the user, it is also important that needleless connectors be designed that minimize the risk of contamination and subsequent infection of the patient.

Question: It is commonly said in the healthcare community that needlestick injuries are caused by the carelessness of healthcare workers or their lack of compliance with universal precautions. In FDA's view, is this an accurate assessment of the cause of most needlestick injuries?

Answer Carelessness and lack of adherence to universal precautions is a contributing factor to needlesticks, but FDA is not aware of data that indicate that this is the predominant reason.

Question: Why did FDA decide to sponsor the August 1992 conference on needle-bearing medical devices? What steps are you taking to ensure participation by healthcare workers who are affected by needlestick injuries?

Page 4 - The Honorable Ron Wyden

Answer FDA is a cosponsor with CDC and OSHA of the August 1992 conference. The impetus of the meeting was the combined regulatory agency desire to take proactive action to address an important healthcare issue. We hope that the meeting will facilitate the creation and availability of devices that help minimize the transfer of bloodborne infections. The meeting is being announced in as many ways as possible by all three agencies to solicit the interest and attendance of healthcare workers and device manufacturers.

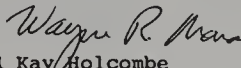
Question: Does FDA plan to initiate rulemaking on a performance standard to ensure that needle-bearing medical devices have safe designs? On what information did you base this decision?

Answer In response to a citizens petition filed on April 19, 1991, by the Service Employees International Union on the same subject, FDA is considering, as one option, initiating rulemaking on a performance standard for needle-bearing devices. Additional detail regarding this matter has been provided in response to your request for information on the petition.

Question: Will you please provide the subcommittee with the latest data from FDA injury reporting systems on injuries involving medical devices with needles.

Answer Enclosed are the Medical Device Reporting Data from the Office of Compliance and Surveillance in the Center for Devices and Radiological Health, together with a summary of the information.

Sincerely yours,


for Kay Holcombe
Acting Associate Commissioner
for Legislative Affairs

Enclosure



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Centers for Disease Control
Atlanta GA 30333

FEB 6 1992

The Honorable Ron Wyden
Chairman
Subcommittee on Regulation, Business
Opportunities, and Energy
Committee on Small Business
House of Representatives
Washington, D.C. 20515

Dear Mr. Wyden:

Thank you for your letter posing questions concerning the use of new needle technology for curtailing the transmission of bloodborne disease in the health-care setting. The Centers for Disease Control (CDC) collaborates with the Food and Drug Administration (FDA) and the Occupational Safety and Health Administration (OSHA) to develop prevention strategies for the prevention of occupational transmission of bloodborne pathogens. Our responses to your questions are enclosed.

CDC, in coordination with FDA and OSHA, is committed to further evaluation of the significance of transmission of bloodborne disease to health-care workers, public safety workers, and others. Needlestick injuries are the largest but not the only potential source of exposure. CDC's emphasis is on preventing percutaneous exposures, that is, a needlestick or cut with a sharp object contaminated with infected blood. We hope that this response provides some insight into our knowledge base and progress to date.

We appreciate the opportunity to respond to your inquiries pertaining to health-care workers. Drs. David Bell and Robert Mullan will be glad to answer additional questions at the hearing on February 7.

Sincerely,

William L. Roper, M.D., M.P.H.
Director

Enclosure

Responses to Questions from
 Congressman Ron Wyden
 Chairman, Subcommittee on Regulation, Business
 Opportunities, and Energy; Committee on Small Business

1. Does CDC have any statistics regarding the frequency of needlestick injuries (NSIs) among health-care workers (HCWs)?

As of December 31, 1991, CDC was aware of 29 health-care workers in the United States who had seroconverted (i.e., previously tested negative on blood test for HIV; later tested positive) to the human immunodeficiency virus (HIV) following an occupational exposure to HIV-infected blood. Of these 29 HCWs, there were 12 laboratory workers, 11 nurses, 3 physicians, and 3 classified as "others." Of these 29 exposures, 24 were percutaneous (i.e., needlesticks or cuts with sharp objects), 4 were mucocutaneous (i.e., mucous membrane or nonintact skin exposure), and 1 was both percutaneous and mucocutaneous.

In August 1983 CDC initiated surveillance of HCWs with occupational exposures to HIV-infected blood. In this ongoing project, as of December 31, 1991, 1,644 HCWs were tested for HIV antibody at least 6 months after the date of the exposure; 3 (0.21 percent) of 1,447 workers with percutaneous injuries seroconverted to HIV. None of the 197 HCWs with mucocutaneous exposures seroconverted in this study.^a

Data have been published regarding the frequency of needlestick injuries among HCWs. Most studies were respondent surveys rather than observational, with the majority directed to hospital workers.

NSIs reported ranged from 34 to 50 percent. Denominator figures were unavailable in many studies. Examples of data reporting include: 189 NSI/1000 HCWs;^b 107 NSI/1000 HCWs;^c and 2,134 exposures/7,065 patient days.^d Additional references are available.

2. Is carelessness or lack of compliance with safety regulations the cause of most needlestick injuries?

NSIs in health-care settings can be attributed to several causative factors. For example, according to research conducted by Dr. Janine Jagger,^e one-third of NSIs are related to two-handed recapping of syringes. Competing hazards (not carelessness), such as the risk of disassembling a device with an uncapped, contaminated syringe, are often cited as reasons for recapping. Despite longstanding recommendations advising against this practice^f and intensified efforts to implement these guidelines, recent studies report disappointing results.^{h,j}

To control NSIs effectively, a collaborative effort among administration, infection control, HCWs, and other pertinent staff is necessary. Safety and infection control guidelines must be established in each health-care facility and supported by the hospital administrators. Implementation of an exposure control plan, as outlined in the OSHA rule, should increase awareness and compliance with prevention strategies.

3. Will OSHA guidelines contribute significantly to decreasing NSIs among HCWs?

CDC collaborated extensively with OSHA in formulating the *Occupational Exposure to Bloodborne Pathogens; Final Rule* (CFR 1910.1030). We concur with OSHA's assessment that "...exposure can be minimized or eliminated using a combination of engineering and work practice controls, personal protective clothing and equipment, training, medical surveillance, hepatitis B vaccination, signs and labels, and other provisions" (p. 64004). A copy of this rule is enclosed for your information.

4. Can needles not intended for injection purposes, e.g., IV connectors, be eliminated altogether or replaced with safer preventive technology?

Numerous devices that preclude the need for needles or other sharps for connection of IV lines are available commercially. Some of these are described in the enclosed *Health Devices* document.

5. What are the factors that may inhibit the development and commercialization of safer needle technologies?

CDC does not have data to define the factors that may inhibit the development and commercialization of safer needle technologies. Needles and needlestick devices are licensed by FDA, and they may be better able to answer this question.

For your information, CDC, FDA, and OSHA are sponsoring the *Frontline Healthcare Workers: A National Conference on Prevention of Device-Mediated Bloodborne Infections*. This conference will be held in Washington, D.C., August 17-19, 1992, and will focus attention on injuries for "sharps" and performance safety of medical devices. A conference flyer is enclosed for your information. Flyers have been sent to all U.S. device manufacturers registered with FDA.

6. Is there a failure on the part of HCWs to report needlesticks?

The literature includes reports that indicate that NSIs are underreported. The CDC guidelines and the OSHA rule have increased emphasis on NSI injury reporting. The OSHA rule defines the procedures to be followed after a report of an exposure incident (p. 64174).

7. How are we to identify the exact moment of infection?

Documentation of an occupational transmission of HIV or other bloodborne pathogens includes documentation of exposure incident, a negative HIV antibody test at time of incident, followed by a documented seroconversion. Details are provided in the OSHA rule (p. 64179).

8. What are the five most pressing issues facing HCW safety regarding NSIs?

Health-care workers are concerned with their own safety and provision of patient care. Pressing issues include, but are not limited to, the development and evaluation of engineering controls to eliminate needlestick hazards (including anti-needlestick devices and gloves that are resistant to such sticks), development of effective post-exposure prophylaxis, effective sharps disposal systems, competing hazards, and job stress.

9. Do you know of any on-going studies currently evaluating the cost-benefit of deploying this new, safer technology?

The New York State Department of Health is currently conducting a study entitled "New York State's Response to Decreasing Needle Stick Risks: Multi-Hospital Study of Devices to Prevent Injury." This study is in response to state legislation passed in 1990 requiring the New York Commissioner of Health to authorize up to 10 pilot studies of devices to prevent NSIs. This study is not yet complete. For further information, you may contact Linda Chiarello, AIDS Program Manager, AIDS Institute, New York State Department of Health, Empire State Plaza, Albany, New York 12237, telephone (518) 474-3045.

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STATEMENT

of the

AMERICAN ASSOCIATION OF NURSE ANESTHETISTS

before the

U.S. HOUSE OF REPRESENTATIVES

COMMITTEE ON SMALL BUSINESS

SUBCOMMITTEE ON REGULATION, BUSINESS OPPORTUNITIES, AND ENERGY

on

HEALTH CARE WORKER SAFETY

FEBRUARY 7, 1992

The American Association of Nurse Anesthetists (AANA) appreciates the opportunity to comment on the topic of health care worker safety. The AANA is the professional society that represents over 24,000 certified registered nurse anesthetists (CRNAs), which is 96 percent of all nurse anesthetists who practice across the United States.

Our testimony will focus on: AANA efforts in health care worker safety, the need for adherence to, and enforcement of, universal precautions, and the development of new, safer medical techniques and devices.

AANA EFFORTS IN HEALTH CARE WORKER SAFETY

Although the issues of Human Immunodeficiency Virus (HIV) and Acquired Immunodeficiency Syndrome (AIDS) are now the subject of increased congressional activity, the AANA has been active for many years in the areas of infection control and prevention of the spread of bloodborne diseases, such as HIV and hepatitis B virus (HBV). In 1989, the AANA published a monograph on *Guidelines for Infection Control in Anesthesia*. This document is currently being updated to incorporate the recently released Occupational Safety and Health Administration (OSHA) final standard entitled, *Occupational Exposure to Bloodborne Pathogens*, which was published in the Federal Register on December 6, 1991. In addition, the AANA HIV/AIDS Task Force developed the *Guidelines on HIV/AIDS Prevention and Management for the Certified Registered Nurse Anesthetist*, which were adopted by the AANA in August of 1991 (Appendix A).

UNIVERSAL PRECAUTIONS

As health care providers, we know that transmission of bloodborne pathogens and other potentially infectious materials can be substantially reduced by strict adherence to universal precautions and infection control policies and procedures. In addition, focused education of health care providers and consumers about the use of universal precautions in the workplace will help reduce the risk of occupational exposure to bloodborne pathogens.

The AANA supports the strict adherence to, and enforcement of, universal precautions, as outlined in the 1991 OSHA Bloodborne Pathogens Standard. The OSHA standard requires employers to implement universal precautions, to educate and train workers on occupational exposure to bloodborne pathogens, and to provide engineering controls and protective equipment to reduce the risk of exposure to potentially infectious materials. In addition, the Centers for Disease Control (CDC) issued a report on July 12, 1991 entitled, *Recommendations for Preventing Transmission of Human Immunodeficiency Virus and Hepatitis B Virus to Patients During Exposure-Prone Invasive Procedures*. In this report, the CDC also emphasized the need for strict adherence to universal precautions, in addition to education of all health care workers.

NEW TECHNOLOGIES

The greatest risk of transmission of bloodborne pathogens and other potentially infectious materials is from a percutaneous exposure, such as a needle-stick. It is estimated that more

than one million accidental needle-sticks occur in health settings each year. Of those, two percent or 20,000 needle-sticks are likely to be contaminated with HIV. Janine Jagger, M.P.H., Ph.D., has conducted research at the University of Virginia on needle-stick injuries, and has found that the cause of most needle-sticks is unsafe needle design. Dr. Jagger concludes that relatively simple design changes can prevent needle-sticks. The reality of exposure to potentially infectious materials from a needle-stick injury is of great concern to anesthesia providers. The AANA is committed to the research and development of medical devices, equipment and techniques aimed at reducing the risk of injury from "sharps" in the workplace, including alternatives to the use of needles.

New technologies do exist today, such as needleless systems and shielded needle alternatives. In fact, if these new devices were being widely used, it is estimated that they could eliminate 50 percent of the needle-sticks that occur. Dr. Jagger has also found that the elimination of unnecessary needles, and the replacement of conventional unsafe needles with protective designs (sheath needles) could result in a 90 percent reduction of needle-sticks from hollow-bore needles. In addition, the New York State Department of Health has also reported a decline in the number of sharps-related injuries as a result of implementing safer delivery systems in their multi-hospital study. The AANA urges the use and availability of these and other safer needle technologies in all health care settings.

Specifically, the AANA supports the development of new technologies such as sheath needles and needleless systems for parenteral and intravenous fluid and drug administration, as well as respiratory, inhalation, intubation, and emergency intervention devices. The development of such systems and devices will reduce the need for anesthesia providers and other health care providers to handle sharp objects and instruments. This will further reduce the risk of puncture injuries.

Direct input from health care providers to developers and manufacturers of technologies, techniques, and enhanced devices designed to prevent the spread of infectious diseases by respiratory or bloodborne means will be advantageous to both the manufacturer and the providers. Input from health care providers will also offer guidance to industrial research and development departments, and potentially enhance the growth of new medical techniques and devices. In addition, collaboration between provider and manufacturer will ensure that the developed product will be more task-oriented, thereby increasing the cost effectiveness of the product.

CONCLUSION

The development of new medical technologies, techniques, and devices designed to prevent the transmission of bloodborne pathogens and other potentially infectious materials, coupled with greater availability of these enhanced products in health care facilities, will ultimately result in improved safety for health care providers and consumers. The protection of health care providers and consumers should be a primary goal of new medical device technologies.

The American Association of Nurse Anesthetists applauds the subcommittee for holding this hearing on health care worker safety. The AANA looks forward to working with Congress,

federal agencies, other health organizations, consumer groups, and device manufacturers to develop new medical technologies, techniques, and devices to decrease the risk of occupational injuries and transmission of potentially infectious diseases to health care providers and consumers.

Thank you for giving consideration to our views on this issue.

**GUIDELINES ON HIV/AIDS PREVENTION AND MANAGEMENT
FOR THE CERTIFIED REGISTERED NURSE ANESTHETIST****INTRODUCTION**

The risk of transmission of the human immunodeficiency virus (HIV) from health care workers (HCWs) to their patients is the subject of much debate. The risk can be described as remote but cannot be quantified precisely. Health care workers are already known to have a small risk of HIV infection from occupational exposure. This risk is much greater than the extremely low possibility of transmission in the opposite direction, from health care worker to patient. The risk of infection from HIV following one needlestick exposure to blood from a patient known to be infected with HIV is approximately 0.5% or one per 200 needlesticks.¹ The probability of transmission from an HIV infected health care worker to a patient during an invasive procedure has been estimated to be between one per 100,000 and one per 1,000,000 procedures.² On the basis of the evidence now available on the risk of transmission of HIV infection from health care personnel to patients, the American Association of Nurse Anesthetists (AANA) remains convinced that Certified Registered Nurse Anesthetists (CRNAs) with HIV infection should be able to continue their normal practice, utilizing rigorous adherence to universal precautions and scientifically accepted infection control practices.

Within health care settings, general infection control procedures have been developed and accepted as a means to minimize the risk of patient acquisition of infection from contact with contaminated materials and devices and of transmission of an infectious agent from health care workers to patients. Such procedures also protect workers from the risk of becoming infected. The guidelines that follow describe the role of barrier techniques and universal precautions in preventing transmission of HIV in health care settings. In addition, these guidelines offer a framework for evaluating HIV infected CRNAs and making decisions about their practice through focusing on the worker's functional abilities and infection control competence.

GUIDELINESI. Universal Precautions

The Centers for Disease Control (CDC) has published practice recommendations to prevent the transmission of bloodborne infections in the health care setting. Recommendations include precautions to prevent parenteral, mucous membrane, and non-intact skin exposure of health care worker to bloodborne pathogens. (Appendix A) Universal precautions should consistently be applied to all blood and body fluids during all aspects of anesthesia care and where the potential for exposure exists.

The AANA strongly recommends that all nurse anesthetists in their practice adhere rigorously to the principles of universal precautions, ie, proper use of barrier precautions, safe handling and disposal of sharp instruments and use of recommended cleaning, disinfection and sterilization techniques in compliance with CDC recommendations. As part of standard infection-control practice, instruments and other reusable equipment used in performing invasive procedures should be appropriately disinfected and sterilized as follows:³

- o Equipment and devices that enter the patient's vascular system or other normally sterile areas of the body should be sterilized before being used for each patient.
- o Equipment and devices that touch intact mucous membranes but do not penetrate the patient's body surfaces should be sterilized when possible or undergo high-level disinfection if they cannot be sterilized before being used for each patient.

- 3 -

- o Equipment and devices that do not touch the patient or that only touch intact skin of the patient need only be cleaned with a detergent or as indicated by the manufacturer.

Since it is not possible to recognize all patients with bloodborne infections, it is recommended that the blood and body fluids of all patients be treated as potentially infectious. Health care workers need to apply these recommended concepts to his/her clinical work setting and understand their responsibility in their role of prevention of transmission of infections. Conversely, the use of barrier techniques, universal precautions and basic infection control practices are essential in preventing the transmission of HIV from an infected CRNA to a patient.⁴

(Note): The published AANA monograph on Guidelines for Infection Control in Anesthesia, 1989, will be revised in 1991 to incorporate any updated CDC recommendations on infection control practices and HIV prevention. These practices include application of appropriate barrier precautions, sterilization and disinfection techniques for instruments or other reusable equipment used in performing invasive procedures.

II. HIV Infected Health Care Professionals

HIV infection alone does not justify the limiting of professional duties unless other factors significantly compromise the ability of the individual to carry out work functions. Decisions about the work responsibilities of HIV-infected CRNAs with evidence of functional impairment or lack of infection control competence should continue to be made on a case by case basis by the individual, the individual's personal physician and the credentialing committee of the facility. Factors that may have a bearing on potential limitation, modification or reassignment of duties for all CRNAs, including CRNAs with HIV-infection, include the following:

- 4 -

1. Illness that may interfere significantly with the CRNAs ability to provide quality care. Both physical and mental competence are to be considered.
2. The immunologic status of the CRNA and susceptibility to infectious diseases.
3. The presence of exudative lesions.
4. Functional inability to preform assigned tasks or regular duties.
5. Documentation or evidence of previous transmission of bloodborne pathogens, including Hepatitis B Virus.
6. Noncompliance with established guidelines to prevent transmission of disease.

Infected CRNAs who perform invasive procedures need to critically evaluate their ability to safely and adequately perform these procedures.

III. Recommendations for Health Care Facilities⁵

Health care facilities should provide training for all CRNAs in the use of barrier techniques and universal blood and fluid precautions. Facilities should regularly review the CRNAs adherence to barrier techniques, universal blood and body fluid precautions and other standard infection control practices. Failure to practice universal precautions is grounds for removal from direct patient care.

CRNAs should be provided or have access to information on HIV risk factors and the merits of voluntary, confidential and anonymous counseling and testing as a personal health measure. Health care facility policies which address the HIV-infected worker should be designed in accord with the following principles: (a) encourage health care workers to learn their HIV status to protect and improve their own health; (b) encourage HIV-infected individuals to seek periodic evaluation for both physical and psychological

- 5 -

limitations that could significantly compromise quality care; (c) encourage HIV-infected health care workers to inform health care facilities when there is a significant risk of compromised patient care or when re-evaluation is appropriate; (d) and assure that limitation of work responsibilities remains individualized, based on functional ability and infection control competence.

IV. HIV Testing of CRNAs

CRNAs who have known risk factors should voluntarily seek HIV testing to protect and improve their own health. Mandatory testing of health care workers for the HIV antibody is not advised. It is cost prohibitive, breaches confidentiality of the CRNA, creates monitoring difficulties, and may lend a false sense of security which has been shown to lessen adherence to universal precautions.⁶

V. Occupational Exposure to Blood and Body Fluids

Facilities have the obligation to provide post exposure testing, counseling, monitoring and surveillance and the option of available and recommended treatment regimens to CRNAs who, although practicing universal precautions, were exposed to blood or body fluids to which universal precautions apply.

All breaks in technique during invasive procedures that result in patient exposure to a CRNAs blood should be documented and reported to designated institutional representatives. If a patient is exposed to body fluids of an infected CRNA, this patient, and only this patient, should be informed of the exposure with maintenance of complete confidentiality of the CRNA. The patient should be offered the same post-exposure testing, counseling, monitoring, and surveillance that is offered to occupationally exposed CRNAs.

VI. Education of the Certified Registered Nurse Anesthetist

The AANA believes that all Certified Registered Nurse Anesthetists (CRNAs) should be educated about and be knowledgeable in universal blood and body fluids precautions, and other scientifically accepted infection control practices. In addition, CRNAs should know the protocols to follow if they are exposed to blood or body fluid from a patient.

SUMMARY

The risk of HIV transmission from an infected health care worker to a patient undergoing an invasive medical procedure is remote, and has not been definitively quantified. Protecting against this remote possibility requires careful adherence to accepted principles of barrier techniques, universal precautions and proven infection control techniques. Health facilities should review with care any procedures in which blood or body fluid contact between workers and patients is a potential risk, in order to ensure compliance with recommended infection control practices and reduce risk of disease transmission. CRNAs who have known risk factors or who have known or suspected occupational exposure should voluntarily seek HIV testing to protect and improve their own health. HIV infection alone is not sufficient to limit professional duties, unless specific factors significantly compromise a worker's ability to provide quality care.

The increasing prevalence of HIV in the general population heightens the risk that health care workers will be exposed to blood and body fluids from patients infected with HIV. Therefore, the AANA strongly urges nurse anesthetists to adhere rigorously to the use of recommended universal precautions in the care of all patients.

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Adopted by AANA Board of Directors August 8, 1991

Appendix A. Update: Universal Precautions for Prevention of Transmission of Human Immunodeficiency Virus, Hepatitis B Virus, and Other Bloodborne Pathogens in Health-Care Settings (Reprinted from Morbidity and Mortality Weekly Report, 1988; 37:377-382,387,388.)

Introduction

The purpose of this report is to clarify and supplement the CDC publication entitled "Recommendations for Prevention of HIV Transmission in Health-Care Settings" (1).

In 1983, CDC published a document entitled "Guideline for Isolation Precautions in Hospitals" (2) that contained a section entitled "Blood and Body Fluid Precautions." The recommendations in this section called for blood and body fluid precautions when a patient was known or suspected to be infected with bloodborne pathogens. In August 1987, CDC published a document entitled "Recommendations for Prevention of HIV Transmission in Health-Care Settings" (1). In contrast to the 1983 document, the 1987 document recommended that blood and body fluid precautions be consistently used for all patients regardless of their bloodborne infection status. This extension of blood and body fluid precautions to all patients is referred to as "Universal Blood and Body Fluid Precautions" or "Universal Precautions." Under universal precautions, blood and certain body fluids of all patients are considered potentially infectious for human immunodeficiency virus (HIV), hepatitis B virus (HBV), and other bloodborne pathogens.

Universal precautions are intended to prevent parenteral, mucous membrane, and nonintact skin exposures of health-care workers to bloodborne pathogens. In addition, immunization with HBV vaccine is recommended as an important adjunct to universal precautions for health-care workers who have exposures to blood (3,4).

Since the recommendations for universal precautions were published in August 1987, CDC and the Food and Drug Administration (FDA) have received requests for clarification of the following issues: 1) body fluids to which universal precautions apply, 2) use of protective barriers, 3) use of gloves for phlebotomy, 4) selection of gloves for use while observing universal precautions, and 5) need for making changes in waste management programs as a result of adopting universal precautions.

Body Fluids to Which Universal Precautions Apply

Universal precautions apply to blood and to other body fluids containing visible blood. Occupational transmission of HIV and HBV to health-care workers by blood is documented (4,5). Blood is the single most important source of HIV, HBV, and other bloodborne pathogens in the occupational setting. Infection control efforts for HIV, HBV, and other bloodborne pathogens must focus on preventing exposures to blood as well as on delivery of HBV immunization.

Universal precautions also apply to semen and vaginal secretions. Although both of these fluids have been implicated in the sexual transmission of HIV and HBV, they have not been implicated in occupational transmission from patient to health-care worker. This observation is not unexpected, since exposure to semen in the usual health-care setting is limited, and the routine practice of wearing gloves for performing vaginal examinations protects health-care workers from exposure to potentially infectious vaginal secretions.

Universal precautions also apply to tissues and to the following fluids: cerebrospinal fluid (CSF), synovial fluid, pleural fluid, peritoneal fluid, pericardial fluid, and amniotic fluid. The risk of transmission of HIV and HBV from these fluids is unknown; epidemiologic studies in the health-care and community setting are currently inadequate to assess the potential risk to health-care workers from occupational exposures to them. However, HIV has been isolated from CSF, synovial, and amniotic fluid (6-8), and HBsAg has been detected in synovial fluid, amniotic fluid, and peritoneal fluid (9-11). One case of HIV transmission was reported after a percutaneous exposure to bloody pleural fluid obtained by needle aspiration (12). Whereas aseptic procedures used to obtain these fluids for diagnostic or therapeutic purposes protect health-care workers from skin exposures, they cannot prevent penetrating injuries due to contaminated needles or other sharp instruments.

Body Fluids to Which Universal Precautions Do Not Apply

Universal precautions do not apply to feces, nasal secretions, sputum, sweat, tears, urine, and vomitus unless they contain visible blood. The risk of transmission of HIV and HBV from these fluids and materials is extremely low or nonexistent. HIV has been isolated and HBsAg has been demonstrated in some of these fluids; however, epidemiologic studies in the health-care and community setting have not implicated these fluids or materials in the transmission of HIV and HBV infections (13,14). Some of the above fluids and excretions

* The August 1987 publication should be consulted for general information and specific recommendations not addressed in this update.

represent a potential source for nosocomial and community-acquired infections with other pathogens, and recommendations for preventing the transmission of non-bloodborne pathogens have been published (2).

Precautions for Other Body Fluids in Special Settings

Human breast milk has been implicated in perinatal transmission of HIV, and HBsAg has been found in the milk of mothers infected with HBV (10,13). However, occupational exposure to human breast milk has not been implicated in the transmission of HIV nor HBV infection to health-care workers. Moreover, the health-care worker will not have the same type of intensive exposure to breast milk as the nursing neonate. Whereas universal precautions do not apply to human breast milk, gloves may be worn by health-care workers in situations where exposures to breast milk might be frequent, for example, in breast milk banking.

Saliva of some persons infected with HBV has been shown to contain HBV-DNA at concentrations 1/1,000 to 1/10,000 of that found in the infected person's serum (15). HBsAg-positive saliva has been shown to be infectious when injected into experimental animals and in human bite exposures (16-18). However, HBsAg-positive saliva has not been shown to be infectious when applied to oral mucous membranes in experimental primate studies (18) or through contamination of musical instruments or cardiopulmonary resuscitation dummies used by HBV carriers (19,20). Epidemiologic studies of nonsexual household contacts of HIV-infected patients, including several small series in which HIV transmission failed to occur after bites or after percutaneous inoculation or contamination of cuts and open wounds with saliva from HIV-infected patients, suggest that the potential for salivary transmission of HIV is remote (5,13,14,21,22). One case report from Germany has suggested the possibility of transmission of HIV in a household setting from an infected child to a sibling through a human bite (23). The bite did not break the skin or result in bleeding. Since the date of seroconversion to HIV was not known for either child in this case, evidence for the role of saliva in the transmission of virus is unclear (23). Another case report suggested the possibility of transmission of HIV from husband to wife by contact with saliva during kissing (24). However, follow-up studies did not confirm HIV infection in the wife (21).

Universal precautions do not apply to saliva. General infection control practices already in existence—including the use of gloves for digital examination of mucous membranes and endotracheal suctioning, and handwashing after exposure to saliva—should further minimize the minute risk, if any, for salivary transmission of HIV and HBV (1,25). Gloves need not be worn when feeding patients and when wiping saliva from the skin.

Special precautions, however, are recommended for dentistry (1). Occupationally acquired infection with HBV in dental workers has been documented (4), and two possible cases of occupationally acquired HIV infection involving dentists have been reported (5,26). During dental procedures, contamination of saliva with blood is predictable, trauma to health-care workers' hands is common, and blood spattering may occur. Infection control precautions for dentistry minimize the potential for nonintact skin and mucous membrane contact of dental health-care workers to blood-contaminated saliva of patients. In addition, the use of gloves for oral examinations and treatment in the dental setting may also protect the patient's oral mucous membranes from exposures to blood, which may occur from breaks in the skin of dental workers' hands.

Use of Protective Barriers

Protective barriers reduce the risk of exposure of the health-care worker's skin or mucous membranes to potentially infective materials. For universal precautions, protective barriers reduce the risk of exposure to blood, body fluids containing visible blood, and other fluids to which universal precautions apply. Examples of protective barriers include gloves, gowns, masks, and protective eyewear. Gloves should reduce the incidence of contamination of hands, but they cannot prevent penetrating injuries due to needles or other sharp instruments. Masks and protective eyewear or face shields should reduce the incidence of contamination of mucous membranes of the mouth, nose, and eyes.

Universal precautions are intended to supplement rather than replace recommendations for routine infection control, such as handwashing and using gloves to prevent gross microbial contamination of hands (27). Because specifying the types of barriers needed for every possible clinical situation is impractical, some judgment must be exercised.

The risk of nosocomial transmission of HIV, HBV, and other bloodborne pathogens can be minimized if health-care workers use the following general guidelines:

1. Take care to prevent injuries when using needles, scalpels, and other sharp instruments or devices; when handling sharp instruments after procedures; when cleaning used instruments; and when disposing of used needles. Do not recap used needles by hand; do not remove used needles from disposable syringes by hand; and do not bend, break, or otherwise

* The August 1987 publication should be consulted for general information and specific recommendations not addressed in this update.

manipulate used needles by hand. Place used disposable syringes and needles, scalpel blades, and other sharp items in puncture-resistant containers for disposal. Locate the puncture-resistant containers as close to the use area as is practical.

2. Use protective barriers to prevent exposure to blood, body fluids containing visible blood, and other fluids to which universal precautions apply. The type of protective barriers should be appropriate for the procedure being performed and the type of exposure anticipated.
3. Immediately and thoroughly wash hands and other skin surfaces that are contaminated with blood, body fluids containing visible blood, or other body fluids to which universal precautions apply.

Glove Use for Phlebotomy

Gloves should reduce the incidence of blood contamination of hands during phlebotomy (drawing blood samples), but they cannot prevent penetrating injuries caused by needles or other sharp instruments. The likelihood of hand contamination with blood containing HIV, HBV, or other bloodborne pathogens during phlebotomy depends on several factors: 1) the skill and technique of the health-care worker, 2) the frequency with which the health-care worker performs the procedure (other factors being equal, the cumulative risk of blood exposure is higher for a health-care worker who performs more procedures), 3) whether the procedure occurs in a routine or emergency situation (where blood contact may be more likely), and 4) the prevalence of infection with bloodborne pathogens in the patient population. The likelihood of infection after skin exposure to blood containing HIV or HBV will depend on the concentration of virus (viral concentration is much higher for hepatitis B than for HIV), the duration of contact, the presence of skin lesions on the hands of the health-care worker, and — for HBV — the immune status of the health-care worker. Although not accurately quantified, the risk of HIV infection following intact skin contact with infective blood is certainly much less than the 0.5% risk following percutaneous needlestick exposures (3). In universal precautions, all blood is assumed to be potentially infective for bloodborne pathogens, but in certain settings (e.g., volunteer blood-donation centers) the prevalence of infection with some bloodborne pathogens (e.g., HIV, HBV) is known to be very low. Some institutions have relaxed recommendations for using gloves for phlebotomy procedures by skilled phlebotomists in settings where the prevalence of bloodborne pathogens is known to be very low.

Institutions that judge that routine gloving for all phlebotomies is not necessary should periodically reevaluate their policy. Gloves should always be available to health-care workers who wish to use them for phlebotomy. In addition, the following general guidelines apply:

1. Use gloves for performing phlebotomy when the health-care worker has cuts, scratches, or other breaks in his/her skin.
2. Use gloves in situations where the health-care worker judges that hand contamination with blood may occur, for example, when performing phlebotomy on an uncooperative patient.
3. Use gloves for performing finger and/or heel sticks on infants and children.
4. Use gloves when persons are receiving training in phlebotomy.

Selection of Gloves

The Center for Devices and Radiological Health, FDA, has responsibility for regulating the medical glove industry. Medical gloves include those marketed as sterile surgical or nonsterile examination gloves made of vinyl or latex. General purpose utility ("rubber") gloves are also used in the health-care setting, but they are not regulated by FDA since they are not promoted for medical use. There are no reported differences in barrier effectiveness between intact latex and intact vinyl used to manufacture gloves. Thus, the type of gloves selected should be appropriate for the task being performed.

The following general guidelines are recommended:

1. Use sterile gloves for procedures involving contact with normally sterile areas of the body.
2. Use examination gloves for procedures involving contact with mucous membranes, unless otherwise indicated, and for other patient care or diagnostic procedures that do not require the use of sterile gloves.
3. Change gloves between patient contacts.
4. Do not wash or disinfect surgical or examination gloves for reuse. Washing with surfactants may cause "wicking," i.e., the enhanced penetration of liquids through undetected holes in the glove. Disinfecting agents may cause deterioration.

5. Use general-purpose utility gloves (e.g., rubber household gloves) for housekeeping chores involving potential blood contact and for instrument cleaning and decontamination procedures. Utility gloves may be decontaminated and reused but should be discarded if they are peeling, cracked, or discolored, or if they have punctures, tears, or other evidence of deterioration.

Waste Management

Universal precautions are not intended to change waste management programs previously recommended by CDC for health-care settings (1). Policies for defining, collecting, storing, decontaminating, and disposing of infective waste are generally determined by institutions in accordance with state and local regulations. Information regarding waste management regulations in health-care settings may be obtained from state or local health departments or agencies responsible for waste management.

Reported by: Center for Devices and Radiological Health, Food and Drug Administration. Hospital Infections Program, AIDS Program, and Hepatitis Br, Div of Viral Diseases, Center for Infectious Diseases, National Institute for Occupational Safety and Health, CDC.

Editorial Note: Implementation of universal precautions does not eliminate the need for other category- or disease-specific isolation precautions, such as enteric precautions for infectious diarrhea or isolation for pulmonary tuberculosis (1,2). In addition to universal precautions, detailed precautions have been developed for the following procedures and/or settings in which prolonged or intensive exposures to blood occur: invasive procedures, dentistry, autopsies or morticians' services, dialysis, and the clinical laboratory. These detailed precautions are found in the August 21, 1987, "Recommendations for Prevention of HIV Transmission in Health-Care Settings" (1). In addition, specific precautions have been developed for research laboratories (28).

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Anesthesia
A special kind
of nursing



A special kind of nursing

Anesthesia is a special kind of nursing, combining the gentle attentions and psychology of superior bedside nursing with the arts of technical nursing and the knowledge of advanced science. Much is required of the professional nurse who enters the field of anesthesia. As a nurse anesthetist, he or she is an essential part of the surgical team. To qualify as an anesthetist, a nurse must be able at all times to command mind, hands, and emotions.

Today's Certified Registered Nurse Anesthetist

A certified registered nurse anesthetist (CRNA) is a registered professional nurse who has graduated from an approved program of nurse anesthesia, and passed a national qualifying examination in order to gain initial certification.

The qualifying examination is the only means by which nurses may become CRNAs. Persons who are qualified to take the examination must meet certain rigid requirements. These include:

- Graduation from an accredited high school or its equivalent.
- Graduation from an accredited program of nursing.*
- Current valid registration as a professional nurse.
- Good moral and ethical standing in the profession.
- Graduation from a program of nurse anesthesia approved by a special accrediting body known as the Council on Accreditation of Educational Programs of Nurse Anesthesia. The duration of the course is usually 24 months, with standards meeting those established by the Council.**

In order to assure high standards of practice, continuing education is mandatory for all CRNAs, and recertification is required every two years.



* In addition, by 1987, the individual must possess a bachelor's degree in nursing or other appropriate science and have a minimum of one year's experience in an acute care area.

** Many programs today offer master's degrees.

A proud profession

Anesthesia is a proud profession with great appeal to the superior graduate nurse. The responsibilities are great, but the satisfactions of accomplishment are many.

Although anesthesia is usually administered in the operating room, the nurse anesthetist may also work in the obstetric department, with psychiatric patients, in the inhalation therapy department, the emergency room, intensive care unit, and in dental offices.

The patient-nurse relationship is probably more important in this field than in any other type of nursing. The well-trained nurse anesthetist supplies the finest of physiologic and psychologic principles, technical skills and theoretical knowledge to each patient with whom contact is made.

About 75 percent of all CRNAs are employed by the hospitals in which they work. Others work in group practice or independently contract their services as they are needed.

Salaries for CRNAs are equal to and usually exceed those of top positions in many types of nursing. A conscientious nurse anesthetist earns the higher salary, however, for no anesthesia situation is without stress; hours are often irregular and the service must be covered 24 hours a day so "call" is inherent in the career of a nurse anesthetist.

Male nurses find this specialty a particularly attractive field for specialization. This fact is emphasized by the high percentage of male nurses who enter this field in relation to other fields of nursing.

The American Association of Nurse Anesthetists (AANA), the professional organization for CRNAs, keeps its members informed of advances made in the science of nurse anesthesia through its publications and educational programs. The AANA sponsors and approves continuing education programs for CRNAs following their initial certification, and provides its members with recognized professional standing.

The first nursing specialty

The role of nurses in anesthesia is almost as old as professional nursing itself. In fact, nurse anesthetists were the first nurses to specialize beyond general duty nursing. Under the direction of Agatha C. Hodgins, the founder of the American Association of Nurse Anesthetists, a group of 49 nurse anesthetists — representing 12 states — met at Lakeside Hospital, Cleveland, Ohio on June 17, 1931 and formed the "National Association of Nurse Anesthetists."

Nurse anesthesia as a career

The need for Certified Registered Nurse Anesthetists is urgent. New hospitals are being built while older hospitals are being expanded to provide for the growing number of patients and the broader scope of today's surgery. These changes in the health care scene add to the ever-growing need for additional, qualified anesthesia personnel.

Today's CRNAs work in all of the states, in the armed services and in many foreign countries. In fact, more than 50 percent of all anesthesia given today is administered by CRNAs.

Nurse anesthesia is undoubtedly one of today's most demanding careers. Nonetheless, it offers a secure and rewarding future to those who are committed to this *special kind of nursing*.



American Association of Nurse Anesthetists
216 Higgins Road
Park Ridge, Illinois 60068
(312) 692-7050

AANA Fact Book

Questions
and answers
about the
American
Association
of Nurse
Anesthetists



American Association of Nurse Anesthetists
216 Higgins Road
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Founded in 1931, the American Association of Nurse Anesthetists (AANA) is a professional organization of some 19,000 registered nurses who have received up to 24 months of postgraduate education in officially approved schools of nurse anesthesia, as designated by the U.S. Department of Health, Education and Welfare, and who have passed a national qualifying examination to achieve the professional designation of CRNA—Certified Registered Nurse Anesthetist.

The following questions and answers should help provide you with a greater understanding of both the AANA and today's CRNA.

Q. What is a nurse anesthetist?

A. A nurse anesthetist is a registered nurse who has specialized in the administration of anesthesia. If a nurse anesthetist's qualifications have been certified as appropriate and proper, the individual may use the initials CRNA after his or her name.

Q. What does CRNA mean?

A. CRNA stands for Certified Registered Nurse Anesthetist. A nurse anesthetist's right to use this professional designation is regulated by the Council on Certification of Nurse Anesthetists, a special certifying body for CRNAs.

Q. Is the profession of nurse anesthesia limited solely to the administration of anesthetics?

A. No. Because CRNAs are highly trained in the areas of respiratory and cardiopulmonary function, they often assist others with these cases. CRNAs assist in the management and resuscitation of critical patients in intensive care, coronary care and emergency room situations.

Q. Where do CRNAs work?

A. About 75 percent are employed by the hospitals in which they work. Others work in group practice or independently contract their services as they are needed.

Q. How do nurse anesthetists differ from anesthesiologists?

A. Anesthesiologists are physicians who have additional education and clinical training in anesthesia. CRNAs are registered nurses who have additional education and clinical training in anesthesia.

Q. Do CRNAs administer much anesthesia in American hospitals?

A. More than 50 percent of all anesthesia given today is administered by CRNAs.

Q. Is nurse anesthesia something new in medicine?

A. Nurse anesthetists were the first nurses to specialize beyond general duty nursing. This specialty was recognized as a legitimate function of nurses nearly 100 years ago.

Q. Why doesn't the public know more about CRNAs?

A. CRNAs have worked behind the scenes in health care and have not sought public recognition. However, the concern for good quality health care at reasonable cost is growing and CRNAs are responding to a public need for more information.

Q. How does a person become a CRNA?

A. The individual must be a graduate of an accredited school of nursing and an accredited school of nurse anesthesia. In addition, he or she must pass a national qualifying examination in order to gain initial certification.

Q. How long does the training take?

A. The length of the programs vary from 18 to 27 months, depending on the school. Most schools are two-year programs and grant certificates rather than degrees, but there is a growing trend toward incorporation of the anesthesia program into a bachelor's or master's degree curriculum.

Q. What does CRNA training include?

A. In-depth studies of anatomy, physiology, biochemistry, pharmacology and physics, and their relationship to anesthesia.

Q. Do CRNAs have to renew their certification?

A. Yes, CRNAs must be recertified every two years by a special body known as the Council on Recertification of Nurse Anesthetists. This council recertifies CRNAs based upon their fulfillment of continuing education requirements and other criteria.

Q. Who accredits schools of nurse anesthesia?

A. In 1952, the U.S. Department of Health, Education and Welfare recognized the American Association of Nurse Anesthetists as the accrediting agency for schools of nurse anesthesia. This followed recognition as the accrediting agency by the American Hospital Association in 1949. Today, schools of nurse anesthesia are accredited by a special body known as the Council on Accreditation of Educational Programs of Nurse Anesthesia.

Q. How many schools does the Council on Accreditation accredit?

A. It accredits about 125 schools in the United States and in Puerto Rico. These schools have an enrollment of about 2,000 students.

Q. How does the AANA assist the schools of nurse anesthesia?

A. The AANA conducts a continuing student recruitment campaign, faculty and curriculum development workshops, and educational seminars. It also assists students with educational loans.

Q. When was the AANA organized?

A. It was organized in 1931 and incorporated in Ohio in 1932 and in Illinois in 1939. The AANA was the first organization formed by registered nurses with postgraduate education in a specialty beyond general duty nursing.

Q. What are the major goals and objectives of the AANA?

A. The AANA's primary goals and objectives are to advance the art and science of nurse anesthesia, to develop and encourage educational standards in the field of nurse anesthesia, and to promote continual high quality anesthesia care.

Q. Does the AANA provide additional services to its members?

A. Yes, the AANA publishes the *AANA Journal*, a professional publication for nurse anesthetists, and the *AANA News Bulletin*, a newsletter highlighting current Association activities. The AANA also sponsors regional workshops, continuing education programs, and an annual education and business meeting. In addition, it offers group insurance programs, placement service through its publications as well as national representation to its members on federal, state and local governmental issues.

Q. Where can I get additional information about the AANA?

A. Contact the AANA Executive Office at
218 Higgins Road
Park Ridge, Illinois 60068
(312) 692-7050

* In addition, by 1987, the individual must possess a bachelor's degree in nursing or other appropriate science and have a minimum of one year's experience in an acute care area.



American Society of Anesthesiologists
statement to
Committee on Small Business
Subcommittee on Regulation, Business Opportunities and Energy

The American Society of Anesthesiologists (ASA), representing more than 30,000 physicians nationwide, is pleased to submit a statement on the occupational exposure of health care workers to possibly contaminated medical equipment and supplies.

The tasks that anesthesia personnel perform in the operating room put them at risk for accidental needlesticks and injuries from other sharp objects. These percutaneous injuries place anesthesiologists and other healthcare workers at risk for infection with bloodborne pathogens including hepatitis B virus, hepatitis C virus and human immunodeficiency virus (HIV). Analyses of blood have demonstrated that the prevalence of markers of hepatitis B virus in anesthesiologists is four to five times that found in the general population, indicating a significantly increased risk of occupational infection for these physicians. Prospective studies of individuals exposed to material infected with HIV have demonstrated that transmission is most likely to occur after accidental needlesticks or percutaneous injuries, although contact with skin or mucous membrane may also be suspect. There is at least one anesthesiologist who has been infected with HIV following an accidental needlestick that occurred while he was inserting a needle into a vein of a patient known to be HIV-positive.

Although the Centers for Disease Control (CDC) has recommended that health care workers use universal precautions and special care when handling needles, survey data indicate that these precautions are ineffective in eliminating accidental needlesticks. Furthermore, these precautions place the burden of protection on the health care worker rather than encouraging the development of safer equipment.

Many investigators have called for improved equipment design either to eliminate the use of needles or to provide passive protective mechanisms for needled or sharp devices. The Occupational Safety and Health Administration's (OSHA) recently published Standard mandates that engineering controls be used to reduce health care workers' exposure to bloodborne pathogens. Safer methods for packaging contaminated needles and other sharp objects should be encouraged to protect those health care workers involved in waste management. For example, needles should not be placed in penetratable containers such as those made of cardboard. Instead, a plastic or other firm material should be used to hold potentially infected "sharps." *

Statement to Committee on Small Business
Page Two

Only a few studies have been published on the effectiveness of needleless or protected needle systems in reducing the frequency of needlestick injuries. Two recent abstracts suggest that these injuries were reduced after implementation of needleless intravenous systems. Unfortunately, many needlestick injuries are not reported and thus the available data may underestimate the true incidence of this type of injury.

Although needleless and protected needle devices are available for many tasks performed by anesthesiologists, needles will continue to be required for anesthetic procedures involving injection through the skin, blood sampling or introduction of catheters and other devices. Therefore, the use of currently available needleless intravenous administration systems will only partially reduce the use of needles and sharp devices in the practice of anesthesiology.

Anesthesiologists are clearly at risk for acquiring bloodborne pathogens during their care of infected patients, as they frequently perform procedures that require needles and sharp devices. Manufacturers should be encouraged to develop devices which offer alternatives to the needled equipment used by anesthesiologists. Once these become available, hospitals would make every effort to provide these safer devices to protect all health care workers at risk.

The ASA would be pleased to work with the Subcommittee on these important issues.

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FAX 708.210.4500

Baxter

January 9, 1992

The Honorable Ron Wyden
Chairman, Committee on Small Business
Subcommittee on Regulation, Business
Opportunities, and Energy
B-363 Rayburn House Office Building
Washington, D.C. 20515

Dear Mr. Chairman:

I'm responding to your recent inquiry regarding the impact worker protection devices may have in curtailing blood-borne diseases. Baxter manufactures and markets a needle-less system (under the trademark InterLink™) that allows doctors and nurses to administer intravenous medications and fluids with a non-needle device. Recent studies by several hospitals using this needle-less system demonstrated that an immediate and significant reduction of needlestick injuries occurred. This empirical evidence of risk reduction supports the use of such products, and as you might expect has generated much enthusiasm among healthcare professionals.

However, the purchase decision for these devices can be difficult and complex, because they are more costly than conventional needle-based products. But one need only dig a little deeper to realize that the benefits of a needle-free system far outweigh the per unit product cost. This is because a reduction in hospital expenses associated with post injury testing occurs concomitantly with a reduction in needlestick injuries. If the unfortunate situation occurs whereby an employee contracts a blood-borne disease as a result of needlestick injury, the cost of treatment would greatly exceed the initial cost of implementation of protective devices.

Needle-less systems should be viewed as an insurance policy to protect healthcare workers from physical risk and the hospital from financial liability. Over time, the price of such products will decline as R&D expenses are re-couped and the market volume increases.

One way to accelerate adoption of worker protective devices is to provide hospitals with clinical data that clearly shows the efficacy of these products. Pilot programs funded by the government such as New York State Needle Legislative Bill NY AB 11001 provide useful information to hospitals considering the use of safer products. Data collected from these pilot hospitals may in some cases alleviate the need to repeat similar testing among other institutions, thereby expediting the implementation process.

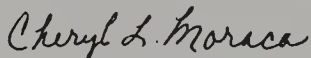
Baxter

January 8, 1992
The Honorable Ron Wyden
Page Two

Baxter will avail itself to support and participate in these types of programs, and will continue to pursue technologies that will enhance a safe work environment for all healthcare employees.

Thank you for your interest in this serious issue which concerns public safety. If I can be of further assistance, please don't hesitate to contact me at 708-270-3768.

Sincerely,



Cheryl L. Moraca
Group Marketing Manager
Access Systems

cmjan8a

cc: Tom Dudar
Lester Knight
Kevin Swan
Tom Dudar

TESTIMONY OF BECTON DICKINSON AND COMPANY
SUBCOMMITTEE ON REGULATION, BUSINESS OPPORTUNITIES, AND ENERGY
RON WYDEN, CHAIRMAN
WASHINGTON, DC
FRIDAY, FEBRUARY 7, 1992

Becton Dickinson and Company manufactures and sells a broad range of medical supplies, devices and diagnostic systems on a worldwide basis. We are the world's leading manufacturer of "sharps" medical devices (including hypodermic needles, syringes, blood collection tubes, IV catheters, and surgical blades).

We share the concern of health care workers that these products, which are intended to treat the illnesses and injuries of patients, do not put the health of caregivers at risk in the process.

Sharps medical devices make it possible for medical professionals to:

- administer medication;
- draw blood for transfusions and diagnostic tests;
- nourish patients unable to eat solid food;
- perform surgery; and many other therapeutic measures which have become an integral part of modern medicine.

Virtually all of these beneficial measures involve puncturing a patient's skin. In order to accomplish their intended function, sharps must be just that: sharp.

Events over the last decade, particularly the advent of AIDS, have focused our attention to include not only the welfare of the patient upon whom the sharps product is used, but also that of the person using the product, and of those who may encounter it "downstream" after its use, such as housekeepers. Given these concerns, we as a company are meeting the challenge of eliminating unnecessary needles where adequate substitutes are available, and creating sharps products which will pierce skin where necessary, but will otherwise minimize or, where possible, eliminate the chance of unintended needlesticks.

We believe that the most effective risk reduction efforts will result from a combination of: more comprehensive user education and training on sharps safety, increased use of safety engineered products and compliance with the recently issued Bloodborne Pathogen standards. We are already beginning to see these elements come together. For example: Many healthcare institutions have begun using comprehensive educational programs, such as Becton Dickinson's Safety Compliance Initiative™. Adoption of newer safety engineered products, such as Becton Dickinson's Interlink™ I.V. Access Cannulas is accelerating dramatically. Our field personnel report high customer interest in achieving compliance with the new OSHA regulations.

The remainder of our testimony responds to the seven specific questions posed in Congressman Wyden's July 17, 1991 letter to Robert Flaherty, President, Becton Dickinson Division.

1. Please describe the dangers posed to healthcare workers from needlesticks and other injuries from sharps medical devices.

Any healthcare facility, by definition, presents an environment which bears an enhanced risk of transmission of infection, both for the patient and the care-giver.

The most current estimate of total U.S. accidental needlestick injuries among healthcare workers is 800,000 annually. It is believed that this figure, although much higher than previous estimates, still represents under-reporting of the actual number of injuries. In a small percentage of cases, these needlesticks will occur following care provided to an HIV or HBV patient.

According to available data and studies, a healthcare worker who incurs an accidental needlestick or "sharps" injury after injecting an HIV (AIDS) positive patient has a 0.6% chance of HIV seroconversion. The risk of HBV seroconversion (Hepatitis B) is estimated at 6%-30%.

The actual risk of seroconversion following a needlestick incident will vary based on the severity of the injury and exposure to blood. Deep puncture wounds or cuts where infected blood from the patient directly enters the healthcare worker's bloodstream will result in the highest risk. A sharps injury from a needle that has not been exposed to a patient's blood (such as a needle used to connect a secondary I.V. line to the upper Y-site of a primary I.V. line) will result in far lower risk.

Both HIV and HBV are life threatening diseases. The known incidence of HIV seroconversion among healthcare workers due to all occupational injuries (needlesticks, splashing, glass breakage, etc.) is relatively low (approximately 45 confirmed cases), but the expected mortality rate is 100%. The known incidence of HBV seroconversion due to occupational injury is much higher (approximately 18,000 annually) - and this disease can still be fatal - though the mortality rate is lower (approximately 200-300 workers will die each year due to HBV seroconversion). However, even when not fatal, HBV will often cause a serious permanent disability.

2. Are federal monitoring systems able to adequately detail the extent of these injuries? Specifically, focus on CDC universal precaution guidelines, OSHA's bloodborne disease standard and the FDA regulatory review process on medical devices.

The ability to adequately detail the extent of these injuries (actual number of occurrences) is principally based on the adequacy of hospital measurement systems and the willingness of healthcare workers to report their injuries. CDC has had a monitoring program since the early '80s to track the progress of healthcare workers who have sustained such injuries. Currently, the adequacy of hospital measurement systems varies by institution, but in general, hospitals are becoming more sophisticated in measuring needlestick injuries. This is likely to improve at a more rapid pace due to the new OSHA bloodborne pathogen standards, since they

require all healthcare facilities to have a reporting and measurement system in place.

Research efforts are currently underway to develop universal needlestick reporting systems. Janine Jagger (University of Virginia) is currently leading this effort. Becton Dickinson has provided a grant for this research.

The CDC Universal Precaution Guidelines provide specific recommendations on how to avoid injury and the need to report and treat needlesticks. The CDC also provides the best available data on the extent of needlestick injuries, though the guidelines themselves are not utilized for this purpose.

The FDA regulatory review process has traditionally focused on the safety and efficacy of medical devices for patients. If any changes in the FDA review process were to be considered, Becton Dickinson recommends they be designed to speed the review of additional needlestick safety products, to help bring these products to market more quickly. The FDA has adopted this posture for drugs that can be used to treat AIDS, and it may also be appropriate for products that can reduce the risk of AIDS transmission.

3. Please discuss the factors that have prompted Becton Dickinson to promote new needles and sharps technology product lines.

A number of factors throughout the 1980s indicated the need to shift sharps product technology to safety product designs. These market factors included the emergence of the AIDS crisis, well publicized cases of seroconversion by healthcare workers, beach wash-ups of medical waste which heightened public concerns, and increasing public pressure to protect patients from HIV infected healthcare workers.

Sensing these trends, Becton Dickinson initiated an intensive safety product development effort throughout the 1980s, leading to introduction of a wide range of new products and product technologies. Included among these new products and technologies are a full line of sharps collectors for safe disposal of sharps without recapping, safety syringes with built-in sliding shields to eliminate the need to recap, safety blood collection needle holders to eliminate the need to recap, blood collection tubes with a unique cap design that helps prevent blood splattering, plastic blood collection tubes to prevent glass breakage, systems that eliminate the need for sharp steel needles for I.V. administration, scalpel blade holders that permit the safe disassembly of blades after use, lancets that automatically retract the sharp point following skin puncture, needles with a permanent safety shield for I.V. administration procedures and more. Generally, a two to five year product development process is required to bring any new technology to market.

To facilitate adoption of these new safety product technologies, Becton Dickinson further invested in comprehensive educational programs to increase awareness of the risk of sharps injury, and to motivate healthcare workers and facilities to seek safety solutions. We also

developed analyses that provide cost justification for the adoption of these new technologies.

We responded based on the strength of market trend indicators and our attempt to anticipate customer needs rather than overt customer demand. We believed that at some point the sharps markets would convert rapidly to safety product designs, and that as the world's largest manufacturer of sharps, we needed to be proactive and help lead this conversion process.

4. In your opinion, what factors inhibit hospitals and other healthcare facilities from the full introduction and implementation of these new, safer technologies?

A number of factors impact the speed of adoption for new medical product technologies. For sharps safety products, these factors include the complexity of hospital sharps usage, the nature of the multi-level hospital decision making process and the need for cost justification.

Complexity of Sharps Usage - Sharps products are utilized for hundreds of hospital procedures. These range from the most basic medical procedures (e.g. injections through the skin) to the most complex (e.g. high pressure injection of radiopaque fluids for diagnostic purposes). To be effective in reducing sharps injury risks while not compromising the efficacy of patient care, new sharps safety products must adapt to each medical procedure, rather than vice-versa. As a result, there is no single, "simple" solution to this problem.

Healthcare facilities, under the new OSHA regulations, will be required to determine which safety products best fit within existing procedure protocols. Once the evaluation process is complete, a broad number of healthcare workers will need to be trained on the use of these new products. Even minor changes in product design or user technique will require extensive training or "inservicing". This is usually done as a collaborative process between the healthcare facility and the product manufacturer.

Nature of Hospital Decision-Making - There is rarely a single decision-maker within a hospital who can institute immediate change. A wide range of individuals, including practitioners, supervisors, purchasing managers, quality control coordinators, administrators and hospital groups are ultimately involved in the decision-making process. As such, the process of instituting change requires broad communication and participation, and generally does not move rapidly in a hospital environment.

Sharps safety products generally involve a moderate extent of change and a large number of involved departments. The urgency of the need for change varies by product and application, ranging from high urgency for sharps collectors (resulting in very rapid adoption), moderate to high urgency for I.V. administration safety products and moderate urgency for safety syringes. In general, the perceived urgency among hospitals for conversion to safety products appears to be increasing dramatically.

Need for Cost Justification - No one disputes the unacceptable human "cost" of needlestick injuries. Hospitals, in addition, operate in a tightly cost constrained financial environment. Adoption of new technologies generally requires a thorough cost analysis process. Despite the higher acquisition price for sharps safety products, mostly due to materials and development costs, we believe that hospitals can generally adopt these products with little or no increase in total usage costs. This is because the higher cost for supplies will be offset by a dramatic reduction in the cost of needlestick post-exposure management.

Studies have documented the cost of needlestick post-exposure management at \$400-\$1,200 per incident (for testing, counseling, screening, prophylactic AZT treatment). The total cost to the U.S. healthcare system for post-exposure management is estimated at \$1 billion annually. These figures do not include the costs of treating healthcare workers who seroconvert. It is estimated that currently available sharps safety product technologies can address over 70% of the accidental needlestick injuries. This potential for injury reductions is the basis of our belief that hospitals can generally adopt these systems without a significant increase in total usage costs, due to the associated reduction in needlestick post-exposure management costs.

5. Do medical training and physician attitudes regarding needles and sharps devices inhibit the acceptance of safer technologies? That is, are physicians and other healthcare professionals hesitant to change their habits, procedures and protocols when it comes to using these new technologies?

Becton Dickinson believes the most successful safer technologies will be those which do not require substantive change in existing hospital procedures. Our safety product offering was designed on this basis. Our goal is to make the safety feature as unobtrusive and passive as possible, and, wherever possible, more convenient to use than the traditional product it replaces. This can help make resistance to change a "non-issue".

Inevitably, use of any new product typically requires some changes in existing habits or protocols. Reaction to these changes for safety products varies among healthcare professionals. Some actively embrace the change because of the safety benefit. Others do not regard the safety risk as serious enough to warrant the change, or accept the risk as an occupational hazard. Usually, the reluctance of these individuals is directly proportional to the amount of change required. Generally, physicians appear to be less concerned about needlestick risks than nurses.

6. Please discuss specific market forces that restrain or limit the development of the needle and sharps device industry. Are these devices prohibitively expensive? Will greater demand and other savings create more cost-effective prices?

The market need for safety products is now very clear. We believe healthcare facilities will broadly convert to sharps safety products. This process is well underway, and the pace has increased rapidly in recent months.

Becton Dickinson is in the forefront in the development of sharps safety products. The development process is complex and usually requires three to five years before viable products emerge for sale. We have an active program to review internal and external product ideas. Each year we formally review hundreds of patents and outside submissions seeking products that meet safety and usage requirements, as well as cost-effective production. Many of the safety products we now offer are based on technologies licensed from external inventors. This investment has resulted in an array of safety products already available, with more new products and improvements in the final stages of development.

Medical supplies represent a small portion of a hospital's total operating expense (less than 10%). "Sharps" products represent a small component of these supplies. Although the prices of sharps safety products are generally higher, the resulting reduction in "post-exposure" management costs will usually offset this increase.

The higher prices for sharps safety products are generally due to additional materials and development costs required for the safety feature. Even with higher levels of demand and production, the prices of these devices will remain above the products they replace. However, high levels of demand will help ensure the most efficient methods of automation and production are utilized, which will result in price levels that provide value and safety for hospitals and healthcare workers.

7. Finally, please discuss the role of U.S. companies as world leaders in developing and marketing these new technologies and whether these technologies will, in time, become the standard of practice.

U.S. medical practice is the most advanced in the world, and the U.S. medical technology industry holds a clear leadership position worldwide. The medical device industry, although small on an overall sales basis (\$34 billion), beneficially impacts the U.S. economy and has a positive trade balance estimated at \$3.7 billion in 1991.

We are proud to be part of a medical device industry that competes effectively on a global basis. By studying our customers' needs and concerns and by applying our American technology, Becton Dickinson has developed superior quality products that have effectively defended our market position in the U.S. against Japanese competition. Simultaneously, we established a strong market position in Asia and other parts of the world. This is a rare example of a U.S. company clearly outperforming its Japanese counterpart.

Currently, 43% of Becton Dickinson's total sales are generated outside the U.S.A. We have business operations, subsidiaries or manufacturing plants in more than 70 locations throughout the world. This exemplifies the U.S.'s continuing role in leading medical technology innovation, and, in transferring the USA's medical technology advantage to other regions of the world.

In many of the world's markets, the U.S. has the opportunity to lead the market development and conversion process, by meeting with local health ministries, holding educational seminars with leading medical professionals and teaching healthcare workers how to improve medical practice. In this manner, we not only transfer product technology, we also take a lead in improving the quality of worldwide medical practice.

This process is well underway for sharps safety products. We have already held educational seminars in many regions throughout the world on sharps safety. We are working with local health ministries to provide education on AIDS and Hepatitis risks, and to establish specifications for safety products. We have introduced, or will introduce in 1992, a full range of sharps safety products and services throughout the world. Although virtually all of these nations will lag the USA's response to the sharps safety issue, we do expect that sharps safety technologies will become a worldwide standard of practice.

Summary

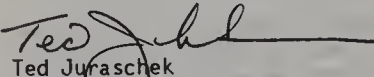
Becton Dickinson is totally dedicated to significantly reducing the risk of accidental sharps injuries worldwide. We have developed a comprehensive system of sharps safety products and educational services. The adoption of our system currently addresses over 70% of the accidental needlestick incidences in a typical hospital. Continued development of new, innovative solutions will likely reduce the incidence of injury even further.

Converting the U.S. market to this system, and launching it on a worldwide basis, is the primary focus of our sharps product efforts. The rate of adoption for BD and other manufacturers' safety products has increased rapidly in the U.S., and we believe the healthcare system will fully convert to these safety products. The issue of AIDS and Hepatitis transmission from patient to healthcare worker (and from worker to patient), the new OSHA standards and hospital concerns over safety, liability and negative publicity appear to be the primary factors which are accelerating the conversion trend.

Becton Dickinson supports public and private initiatives to call attention to the issue of sharps safety. We believe these initiatives can help further accelerate the rate of safety product adoption. We do not believe additional regulation is necessary to achieve this goal. In some circumstances, we believe regulation could complicate the adoption process or stifle the degree of technical innovation.

We are pleased to have been given this opportunity to describe our sharps safety system and present our views to the subcommittee. We look forward to continued interaction as we work towards the common goal of enhancing healthcare worker safety.

Sincerely,


Ted Juraschek
Director
Government Relations

For additional information or clarification, please contact:
Becton Dickinson Corporate Communications
Telephone: 201-847-6731
Fax: 201-847-5305

Safety Compliance Initiative is a trademark of Becton Dickinson and Co.
Interlink is a trademark of Baxter Healthcare Corp.

CRITIKON

a Johnson-Johnson company

Champion of Innovative Products and Services Unparalleled in Customer Value

Office of the
President

January 8, 1992

The Honorable Ron Wyden
United States House of Representatives
Committee on Small Business
Subcommittee on Regulation, Business Opportunities and Energy
B-363 Rayburn House Office Building
Washington, DC 20515

Dear Representative Wyden:

Thank you for asking for our help in your effort to understand the issues surrounding the implementation of accidental needlestick prevention devices in the hospital and healthcare environments.

To that end, we offer the following information:

- * At present, we see no true regulatory, structural or procedural roadblocks impeding the sales and marketing of accidental needlestick prevention devices. Our device, the PROTECTIV[™] I.V. Catheter Safety System, is being very well received in the hospital and healthcare marketplace.

We do see, however, the potential for regulation to help in raising awareness, usage, and accelerating the implementation of safer needle bearing devices. For example, recently adopted OSHA guidelines call for a number of activities to prevent contact with bloodborne pathogens in healthcare workers. Universal Precautions, mandatory HBV vaccinations, sharps container programs, etc. are all very necessary and OSHA is to be applauded for following CDC recommendations in adoption of their rules. We feel, however, that policy makers should also pay attention to engineering controls that would result in better designed products in the marketplace, because better products can also reduce the accidental needlestick problem. An analogy could perhaps be drawn by suggesting that injuries in automobile accidents could be reduced or eliminated by more aggressive safe driving campaigns rather than by the use of seat belts.

We also see attitudes of managing for the short-term rather than long-term being an impediment to implementation of safer devices. Healthcare administrators and professionals today are under tremendous pressure to control the daily cost of health care. Most reimbursement programs today tend to be "flat fee based." Therefore any product that raises the unit cost of a supply item

Honorable R. Wyden
Page Two

is looked at with suspicion and skepticism and it takes a real education process, usually conducted by the manufacturer, to show the health administrator and professional the "value" of safer products. For example, we must convince healthcare providers that the real cost of accidental needlesticks is far greater over time than the incremental cost of the new technology. In some cases we are successful, but in many cases the cost containment pressure is so great that the potential buyer continues to look only at unit costs and ignore the more important big picture, including the health and safety of the healthcare worker.

- * There are a number of independent research efforts underway which are designed to assess the effectiveness of almost all needlestick prevention devices. Also, a number of states have passed legislation which commissions a study of the effectiveness and a critique of the usefulness of safer devices. Our PROTECTIVtm I.V. Safety System is included in a number of these research efforts.

We conducted extensive end user market research efforts as well as a number of customer focus groups to obtain input into the design of our product. We extensively test marketed the product prior to launch. In fact, the product we are marketing today is a second generation product born out of customer feedback.

To date the biggest complaint or criticism of our product (as well as virtually every other safety product of which we are aware) has been price. However, as stated earlier, once the buyer appreciates all the costs associated with an accidental needlestick, many of these price objections are overcome.

In addition, the end-user must learn how to use the new products and frequently buyers must be convinced that the investment in re-education regarding new technologies will be recouped.

- * Critikon has put together a program which allows health care professionals to assess the cost effectiveness of any needlestick safety product based upon data pertinent to their particular circumstances. The program entitled "Clinical Implication and Financial Impact of Accidental Needlesticks," has been well received by the health care community. This "risk/benefit analysis" allows the institution to compare their accidental needlestick treatment protocols with those recommended by the CDC, then assign costs to each of those treatment steps. The program then goes on to point out some of the hidden costs one might consider when measuring the impact of an accidental needlestick and assign "value" to any number of hidden expenses. Some of these hidden costs are: actual medical costs of treating an injured worker, increased insurance rates, OSHA fines, legal fees, lost time, replacement of injured workers, increased recruitment costs, etc.

To our knowledge, Critikon's program is one of the most widely used and accepted tools for assessment of the cost impact of safer needle technologies. It is unique in that it not only provides a

Honorable R. Wyden
Page 3

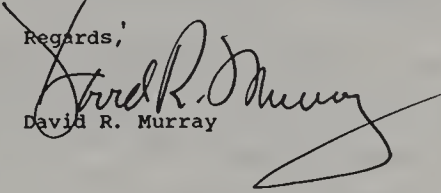
vehicle to measure direct costs associated with accidental needlesticks, but the hidden costs mentioned earlier. A copy of this program is enclosed for your review.

To assess the cost impact of the new needlestick prevention technologies available today is a complex process. The degree of "value" these products bring to the marketplace depends on whether one assigns dollars to some of the "human issues" surrounding an accident of this nature. If one assigns value to these types of issues then the new technologies are usually less costly than the products they replace. However, if one only looks at real, nonhidden, non-human costs, these new, safer technologies tend to cost somewhat more than the products they replace.

- * The widespread adaptation of safer needle technologies would tend to lower costs and prices associated with these products. Whenever one deals with high volume disposable or single use products, volume has an impact on cost and price. This is simply because of overhead and development cost absorption being spread across a larger numerical base. However, we would also point out that Critikon has priced the PROTECTIVtm I.V. Safety System on the basis of projected future costs not actual costs in order to make our product as "affordable" as possible.

We hope this information is helpful to you. If you require more information, if any of our answers require elaboration or clarification, feel free to contact me at any time. Again, we applaud your effort to gain input from health care safety device manufacturers on this most important issue. If there is anything else we can do to help, please advise.

Regards,


David R. Murray

Enclosure

Page 1 of 10

SUSAN L. ENGEL-ARIELI, M.D.

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PARK RIDGE, ILLINOIS 60068
TELEPHONE (708) 692-2207

2/10/92

Dear Chairman Wyden & Members of the Subcommittee on Regulations,

I spoke with Mr. Foren today regarding the Subcommittee on Regulation's hearings on health care workers contracting serious illnesses from needlesticks in the medical care setting.

I was so heartened to hear of your interest in this matter. I only wish that I knew sooner so I could have contacted you earlier. I first learned of your efforts on CNN on Friday evening.

I am a 37 year old physician, who wanted to be a doctor since I was seven years old. I worked hard towards that goal ever since. I studied very hard, sacrificing many things, and taking out large loans. I started doing cancer research since the age of eleven, published since the age of 15 years old and won many awards including Ten Top Tomorrow Scientists & Engineers, Ten Top College Women of the Nation, Most Prominent Student of the Nation, and many more.

SUSAN L. ENGEL-ARIELI, M.D.

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In October of 1987, I was working as a medical resident in Internal Medicine at a Midwestern Hospital. On the tenth day of that month I was called to one of my patient's room to draw blood. The medical student had tried, but failed to draw the blood. I requested that a nurse help me hold down the patient's arm. I drew the blood and handed the syringe to the nurse - whereby she began injecting blood into empty test tubes. I was busy adjusting the patient's oxygen mask and holding a gauze pad over the site where her blood had been drawn. The nurse came towards me (for no apparent reason) and seemed to trip - plunging the syringe into my left hand and pushing the plunger whereby blood was injected into my hand. I washed my hand & disinfected it with alcohol. Although I knew the patient had encephalitis (a serious brain infection) - I hoped that nothing adverse would happen to me.

I was wrong in hoping this. Within 24 hours I developed symptoms and within

page 3

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a few more days, a diagnosis of encephalitis was made in my case.

I have developed severe inner and middle ear problems including endolymphatic hydrops in both ears, perilymph fistulas in both ears, BPPV in both ears; Brainstem problems; immunologic problems (such that every 2-3 weeks I develop flus, pneumonias, etc - resulting from a low white blood cell count and low lymphocyte count); resulting heart valve problems; and several herniated neck discs with spinal cord and nerve impingement. All of this was a result from the needlestick accident.

I have come close to death several times and remain home bound and often bed-bound. I have had over \$200,000 in medical bills and require an assistant to come in and help me with many tasks.

It does not, at this time, appear likely that I will ever be able to work outside of the home, let alone complete my medical

Page 4

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Training and practice as a physician. My career is destroyed as well as the chance for a family. My husband has been emotionally affected by this, as well as my mother. I have constant and high medical bills, my husband's small company is not doing well and he is close to bankruptcy.

My hospital refuses to help me in any way, has not paid any medical bills, has offered no encouraging words, and refuses to help out with workman's compensation. This is an extremely typical situation - as I'm sure can be also addressed by Dr. V. Prego, Dr. Hacıb Aoun and others.

This situation has been catastrophic for myself, my family, and other health care workers.

page 5

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I would like to suggest the following recommendations for your Subcommittee and others to consider:

1) Definitely tighten the workman's compensation laws so that physicians, nurses, medical technicians, janitors, and others who get stuck can collect compensation. There may be health care workers who have succeeded in obtaining this, but I don't know any!

The hospitals, who have unlimited money, hire the best lawyers, and find all loopholes so that judgments are not made against them.

Something must please be done about this, because the results are biased and terribly unfair. Dr's Prego and Aoun have succeeded in lawsuits against their hospitals - but only after much struggle, discrimination, and after very very aggressive and successful

page 2

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media campaigns. It is true that they were able to be awarded much larger sums of money (than with w-c) but not every one can succeed.

One of the California nursing groups has been fighting for some changes in workmens comp issues for needlestick accidents & I believe they have had some success - but this would be better addressed nationally.

2/ Although Universal Precautions are necessary and should be preserved, they do absolutely nothing to protect the health care worker from needlestick accidents.

This however does bring up a point that I believe OSHA should consider. Institute penalties for hospitals and their staff members who try to discourage other health care workers from doing universal Precautions. This is still being used as a tactic by hospital supervisors.

page 7

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3) The main way to correct the problem, is to prevent the problem. I understand there are safer devices on the market, but most hospitals/clinics refuse to buy them because they are more expensive.

If the FDA and/or OSHA could study the problem, determine the inherent dangers of needlestick accidents, (both for the general public and health care workers) and suggest the use of safer devices - this would be of ultimate good use.

4) It would be very helpful if NIH, OSHA, or another agency could fund (along with device companies) more research on the development of still safer hospital injectable items. This would basically include IV needles, butterfly needles, syringes with needles, arterial blood gas needles. The danger comes not

page 8

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with the possible needlestick before it is injected, but after it has been withdrawn from the patient or infected tissues.

Further guards & sleeves need to be designed to quickly cover the sharp part of the needle, once removed from the patient or tissue.

New ideas need to be explored with regards to making surgical scalpels and suture material more safe. This may require both technical and educational (physician and nurse) approaches.

As an addendum the hospital product industry needs to address the safety of blood culture bottles, tubes and other materials. I have often heard that these explode, spraying blood or tissue in the health care workers face & eyes, and on occasion bursting small pieces of glass with contaminated blood into the health care workers body. I believe this would best

page 9

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be addressed by the FDA reporting on the numbers of exploded products. It should be mentioned that this is currently underreported.

5) Education is important, but in my mind, not as crucial as the above items.

You can be very educated in safety matters, and yet tragic mistakes and human error can still happen.

With that said, I believe it is still crucial that all hospital employees should be given an intensive safety course on handling infectious materials, handling needles, and etc. As of early 1989, this was not being done. I don't know if it is now, but if it isn't, perhaps OSHA could insist that all hospitals and laboratories provide this on a regular basis (say 1x per year) and to all new employees. This might have prevented Dr. Prego from becoming ill with a needle that was left in a bed, or in my case where a nurse was

page 10

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walking around with a contaminated,
uncovered needle.

I sincerely hope you will
consider these important problems, and
I greatly appreciate your concern and
help.

If there are any questions or
comments, please do not hesitate to
call or write me?

Enclosed is a copy of my C-U.

I would greatly appreciate any reports
or information you could send me on
the conclusions, results, etc. of this
Subcommittee and its counselors.

Again, many many thanks.

Sincerely,
Susan L. Engel MD

CURRICULUM VITAE

NAME: Susan Lee Engel, M.D.

DATE: December 1991

HOME ADDRESS: 1026 North Knight
Park Ridge, Illinois 60068

HOME PHONE: (708) 692-2207

ACADEMIC BACKGROUND:

Institution	Period	Major	Degree
Northwestern University Evanston, Illinois	1972- 1975	Biology	B.A.
UHS/The Chicago Medical School North Chicago, Illinois	1978-1982	Medicine	M.D.
Internship - Rush Presbyterian St. Lukes Hospital Chicago, Illinois Lutheran General Hospital, Park Ridge, Illinois	1982-1983	6 Mo Surgery 6 Mo Medicine	PGY-1
Internship - Residency Northwestern Medical Center Chicago, Illinois	1987-1988	18 Mo Medicine	PGY-1

PROFESSIONAL EXPERIENCE:

6/86 - Manager Product Complaint Analysis (PCA) Group,
6/87 Abbott Laboratories, North Chicago, Illinois.

- * Managed PCA group and assured regulatory and company compliance with respect to 2000+ medical drugs and devices.
- * Reviewed and critiqued protocols from research group on new and marketed products.
- * Managed computer assistance for PCA group.
- * Managed queries and trending of product complaints.

Susan Lee Engel
Curriculum Vitae
Page 2

December 1991

1986 - Director, CNS Clinical Research, R&D, G.D.
(1st & Searle & Company, Skokie, Illinois.
2nd Qtr.)

- * Established clinical CNS Group, which included management of personnel from corporation acquisitions.
- * Defined structure and clinical development plans for CNS compounds.
- * Completion of amendments, incorporation of standard operating procedures of studies, and familiarization with direct database entry system.
- * Preparation of FDA Annual Report.

1984 - Director, U.S. Regional Clinical Support, R&D,
1986 G.D. Searle & Company, Skokie, Illinois.

- * Defined structure and goals, organized, hired all personnel and carried out development of a new group. This group was a pioneer joint effort between marketing and R&D which concentrated its efforts on G.I. research.
- * Had extensive experience in preparing budgets, tracking studies, designed new Phase III protocols including emergency use studies and successfully directed completion of several studies.
- * Had expertise in dealing with both marketing and R&D simultaneously, chaired monthly meetings with both, presented at major medical symposia, entertained visiting medical dignitaries, and had interface involvement with Public Relations.
- * Assisted Vice President in preparing speeches and substituted for V.P. during absences.
- * Helped in a major degree with respect to preparation for FDA meeting to support an NDA.
- * Analyzed potential for licensing new drugs, reviewed medical protocols, final reports and papers for possible publication.

Susan Lee Engel
Curriculum Vitae
Page 3

December 1991

- 1983 - Associate Director, Gastroenterology, Clinical
1984 Research, G.D. Searle & Company, Skokie, Illinois.
- * Planned and coordinated research projects in Gastroenterology Division.
- 1982 Clerkship, International, G.D. Searle & Company,
Skokie, Illinois.
- * Aid in the planning of protocols.
- 1982 Extra-Intracranial Arterial Bypass (EiAB) Surgical
Study, University of Vienna, Austria.
- * Collected and studied effects of EiAB on 410 patients.
- 1980 Rheumatoid Arthritis Study, Lutheran General Hospital,
Park Ridge, Illinois.
- * Studied possible correlates with kidney disease.
- 1978 Oncological Virus Study, University of Wisconsin,
Madison, Wisconsin.
- * Worked with Dr. Temin's ongoing research in that area.
- 1977 - Ligament Transplantation Study, VAH Hines and Loyola
1978 University, Maywood, Illinois.
- * Studied bone-ligament-bone transplanation of dogs.
- 1977 Osteoblastic Growth Study/Dr. Claude Gendreau, DVM
Chicago, Illinois.
- * Coordinated research on bone growth in dogs.
- 1974 - Astro-Bioqeophysics Study Northwestern University,
1975 Evanston, Illinois.
- * Studied various modes of circadian rhythms.
- 1974 Research Editorial Assistant, University of Chicago,
Chicago, Illinois.
- * Reviewed articles for possible journal publication.

Susan Lee Engel
Curriculum Vitae
Page 4

December 1991

- 1973 Genetics Studies/Dr. Robert King's Lab, Northwestern University, Evanston, Illinois.
- * Worked with mutant strains of *Drosophila melanogaster*.
- 1972 - Medical Technician/Toxicology Department, G.D. Searle & Company, Skokie, Illinois.
- 1973
- 1970 - Oncological Research, University of Chicago, Chicago, Illinois.
- 1972
- * Studied implant device efficacy of Ehrlich Ascites carcinoma in animals. Cytosar used as primary therapeutic agent in device.
- 1967 - Oncological Research, Lutheran General Hospital, Park Ridge, Illinois.
- 1971
- * Worked with Thiotepe in Ehrlich Ascites carcinoma in mice.

FACULTY APPOINTMENTS:

- 1987 - Assistant Professor of Medicine in Service Series,
- 1991 King Drew Medical Center, UCLA, Los Angeles, California.
- 1987 - Associate Investigator, King Drew Medical Center, Los Angeles, California.
- 1991
- 1985 - Associate on the Complimentary Faculty of the Department of Pathology, Rush Presbyterian St. Lukes Hospital, Chicago, Illinois.
- 1986
- May Visiting Professor, Rush Presbyterian St. Lukes Hospital, Chicago, Illinois.
- 1985

EDITORIAL BOARD APPOINTMENTS:

- 1986 - Internal Medicine
- 1990
- 1987 - Vantage Council Publication of American Academy of Medical Directors
- Ongoing

Susan Lee Engel
Curriculum Vitae
Page 5

December 1991

LICENSURE: State of Illinois

PUBLICATIONS AND/OR HONORS:

Publications: 6 (See Attached List)

Honors: 27 (See Attached List)

MEMBERSHIP IN PROFESSIONAL SOCIETIES:

American Academy of Medical Directors
American Association for the Advancement of Science
American College of Physicians
American Federation for Clinical Research
American Medical Association
Chicago Medical Society
Illinois State Medical Society
Southern Medical Association

PROFESSIONAL ACTIVITIES:

1991 - Board of Directors, American Society of Handicapped Physicians
Ongoing
1989 - Board of Directors, Vestibular Disorders Association
Ongoing
1987 - Advisory Committee on Public Health Policy
1991 Chicago Medical Society Council

REFERENCES: Available upon request.

Susan Lee Engel
Curriculum Vitae
Page 6

December 1991

PUBLICATIONS:

- Newman, R.; Gitlin, N.; Lacayo, E.; Safdi, A.; Ramsey, E.; Engel, S. Misoprostol in the Treatment of Duodenal Ulcer Refractory to H₂ Blocker Therapy, The American Journal of Medicine, Vol. 83 (suppl 1 A): 27-31, July 27, 1987.
- Engel S.L.; Tapper, E.J.; Oleata, R.; Rodriguez, A.; Ramirez M.; Gutierrez, I.; and Hernandez, J.: Use of Open Label Misoprostol in Severe and Emergent Refractory UGI Disease and in Diffuse Gastric Bleeding, Symposium held in Algarve Portugal, September, 1984.
- Vorkapic, R.; Pendl, G.; Koos, W.Th.; Reisner, T.; and Engel, S.L.: CT Scanning for Long Term Follow-Ups After Microsurgery for Posterior Fossa Tumors in Children. Advances in Neurosurgery, Vol. II; 282-287, 1983.
- Engel, S.L.: Indications and Results for 410 Cases of EIAE (Extra-Intra-Cranial Arterial Bypasses). International Surgery, 68 (3): 197-201, 1983.
- Engel, S.L.: Effect of Implanted Cytosar-Silicone Complex on Ehrlich Ascites Carcinoma in Mice. Clinical Research 22 (4): 672A, 1974.
- Engel, S.L.: Effect of Implanted Cytosar-Silicone Complex on Ehrlich Ascites Carcinoma of Mice. American Journal of Medical Technology, 32 (5): 175-178, 1973.

HONORS:

- 1988-1991 Who's Who in the World
- 1988 International Cultural Diploma of Honor
- 1987-1991 Who's Who in the Midwest
- 1987 2000 Notable American Women
- 1982 Top Medical Student Neurology at UHS/The Chicago Medical School
International College of Surgeons National Fellowship,
Chicago, Illinois

Susan Lee Engel
Curriculum Vitae
Page 7

December 1991

- 1976 Most Prominent Student of the Nation, Gatlinburg, Tennessee
- 1975 One of Top Five Students at Northwestern University,
Evanston, Illinois

Graduated with "Honors Biology," Northwestern University,
Evanston, Illinois
- 1974 One of Ten Top College Women of the Nation, New York, New York
Mortar Board Honorary Society, Evanston, Illinois
- 1973 Shi Ai Women's Honorary Society, Evanston, Illinois
- 1972 One of Ten Top Tomorrow's Scientists and Engineers,
Standard Oil Company, New York, New York

NASA-NSTA Award, Cleveland, Ohio

U. S. Navy Medical Award

U. S. Air Force Award

U. S. Army Award

Standard Oil (Indiana) Award

Illinois and American Veterinary Medical Association Award

Kodak Company Award

Illinois State Microscopical Society Award

Bausch-Lomb Award

Junior Citizen Award

Veterans of Foreign Wars Speech and Writing Award

Chicago Tribune, Literary Awards

National Committee for Careers in Pathology and Medical
Technology Award
- 1969 G. D. Searle Science Exposition Award

December 1991

CHARITY/COMMUNITY ACTIVITIES:

A. BOARD OF DIRECTOR SEAT APPOINTMENTS/CONTINUED INVOLVEMENT ACTIVITIES:

- 1991 - Acting Vice President, Co-Chmn Fundraising, Contributor to
Ongoing Newsletter of American Society of Handicapped Physicians
- 1989 - Fundraising Co-Chmn and Column in Newsletter for Vestibular
Ongoing Disorders Association
- 1988 - Auxiliary Board of Directors of President's Council, and
Ongoing Executive Committee, School of Art Institute of Chicago
- 1988 - Board of Governors and Deputy Governor of American Biographical
Ongoing Institute Research Association, Raleigh, North Carolina
- 1988 - Research Board of Advisors, American Biographical Institute,
Ongoing Raleigh, North Carolina
- 1988 - Board of Midwest American Austrian Society
Ongoing
- 1985 - President's Committee of Landmark Preservation Council of
1989 Illinois, Chicago, Illinois
- 1985 - Governing Member, Art Institute of Chicago
Ongoing
- 1982 - Sustaining Fellow, Art Institute of Chicago
Ongoing
- 1983 - Board of Directors, Chicago Boys and Girls Club, Marshall Unit
Ongoing

B. COMMITTEE INVOLVEMENTS:

- 1988 Auction Co-Chairman & Patron Co-Chairman for Chicago
Opera Theatre Anniversary Benefit
- 1988 Auction Co-Chairman & Patron Co-Chairman for Hubbard Street
Dance Company Anniversary Benefit
- 1987 Auction Committee Victory Gardens Theatre, Chicago, Illinois
- 1986 Benefit Committee for Chicago International New Art Forms
Exposition, Art Institute of Chicago

Susan Lee Engel
Curriculum Vitae
Page 9

December 1991

- 1985 - Rush-Presbyterian St. Lukes Hospital, Anchor Cross Society Member
Ongoing
- 1986 - Travel Committee for Art Institute of Chicago
Ongoing
- 1985 Committee for Fantasy Auction V for the School of the Art
Institute of Chicago
- 1984 - Vice Chairman, Capital Campaign to raise \$46 Million,
1985 Art Institute of Chicago
- 1983 - Sustaining Fellow Membership Committee of the Art Institute of
1988 Chicago

C. POLITICAL INVOLVEMENT:

- 1986 Vice Chairman of Committee for former Ambassador to U.N.
- 1986 Vice Chairman of Committee for wife of Vice-President of U.S.
- 1986 Active involvement in primary for state representative,
Cook County Sheriff and national senatorial races.
- 1982 - Congressional advisor to local Congressman
Ongoing

* * * * *

**Federation of Nurses and
Health Professionals** AFL
CIO

555 New Jersey Avenue, NW
Washington, DC 20001
202/879-4491

ALBERT SHANKER
President



February 12, 1992

Graydon John Forrer
Room B-363 Rayburn
Washington, DC 20515

Dear Grady,

Elaine Shocas asked that I send an additional copy of our "remarks" on health care worker safety to your office. (I believe we faxed a copy to Matt Levinson on Monday.) You will find the remarks enclosed.

As you review our remarks, please note in particular our concern over both the rising incidence of tuberculosis (especially in HIV-infected persons) and how this may be of concern when considering bloodborne diseases. This is an angle I don't believe I heard covered in any other remarks.

If you have any questions, or would like to talk further, please give me a call. We remain very interested and active on this issue and look forward to further opportunities to work together.

Sincerely,

Katherine Kany

Katherine Kany
Professional Issues Coordinator

Enclosures

KK:mk
opeiu2/afl-cio

STATEMENT OF CANDICE OWLEY, RN
 VICE-PRESIDENT, AMERICAN FEDERATION OF TEACHERS
 DIVISIONAL CHAIR, FEDERATION OF NURSES & HEALTH PROFESSIONALS
 ON HEALTH CARE WORKER SAFETY
 SMALL BUSINESS COMMITTEE
 SUBCOMMITTEE ON REGULATION, BUSINESS OPPORTUNITIES AND ENERGY
 FEBRUARY 7, 1992

Mr. Chairman and Members of the Committee:

I am Candice Owley, Vice President, American Federation of Teachers and Chair of its health care division, the Federation of Nurses and Health Professionals. On behalf of the over 40,000 members of the Federation of Nurses and Health Professionals (FNHP), I would like to thank you for this opportunity to offer testimony on the problem of worksite exposure to severe and life threatening illnesses like AIDS, hepatitis and tuberculosis through needlestick injuries. Our membership comprises primarily RNs and other health professionals who work in acute care settings. Many also work in correctional institutions, visiting nurse associations and long-term care facilities.

We present testimony for two important reasons. First, we can corroborate the stories that you will hear today with the experiences of our members who have experienced needlestick injuries. Second, we feel that our members' accounts will demonstrate the need to strengthen existing OSHA standards and CDC guidelines that protect health care workers from blood-borne diseases and encourage adoption of measures, like those proposed to

the Food and Drug Administration by the Service Employees International Union, for performance assurance standards for safe needle devices.

The urgency for taking such measures becomes even more apparent when you consider the new research on the epidemic of tuberculosis among HIV-infected individuals. You might ask how tuberculosis is related to needlestick injuries. For some time, there has been research documentation that the *Mycobacterium tuberculosis* bacterium can be transmitted from an accidental needlestick injury.¹ Until recently, this form of transmission was seen as such a rare event that it was viewed as insignificant. Now, in light of recent research on tuberculosis infection among HIV-infected individuals, we may have to consider TB in certain clinical settings as a blood-borne disease. In a recent article in The New England Journal of Medicine, Barnes et al. comment that the "most striking clinical feature of tuberculosis in patients with HIV infection is the extremely high frequency of extrapulmonary involvement [involving tissues and organs outside the lungs] usually with concomitant pulmonary tuberculosis."² It

¹ Sahn, S.A. and D.J. Pierson, "Primary cutaneous inoculation drug-resistant tuberculosis." American Journal of Medicine, 1974; 57: 676-678

² Barnes, P.F., Block, A.B., Davidson, P.T. and D.E. Snider, "Tuberculosis in Patients with Human Immunodeficiency Virus Infection." The New England Journal of Medicine, 1991, vol. 324, no. 23: pp. 1644-1650

FNHP Testimony

- 3 -

is estimated that extrapulmonary TB is seen in more than 70 percent of patients with TB and preexisting AIDS, and 24 percent to 45 percent of patients with tuberculosis and less advanced HIV infection. Blood from patients with extrapulmonary tuberculosis carries the bacteria that can infect others.

These findings have serious implications for our health care professionals who work in urban acute care facilities and correctional settings that have populations with a high prevalence of HIV infection. Our visiting nurses in New York City who care for HIV-infected individuals will also be affected. All of these workers are acutely aware of their exposure to pulmonary tuberculosis in poorly ventilated prisons and hospitals; many have already skin-converted, that is have tested positive for tuberculosis, and must cope with prophylactic treatment to prevent full-blown tuberculosis. Now, they must also face the prospect that an accidental needlestick injury from an HIV-infected individual could mean not only potential exposure and infection with HIV but also with mycobacterium tuberculosis.

We are currently investigating a report from a member who contends that she contracted TB through a needlestick injury.

Needlestick Injuries: A Common Occurrence for FNHP Members

The specter of blood-borne diseases long ago convinced FNHP that eliminating needlestick injuries should be a top priority. We have worked to find out how these injuries occur and to educate members about several aspects of needlestick injuries: 1) the importance of following CDC guidelines, 2) the importance of reporting workplace injuries and getting follow-up care, 3) the importance of getting hepatitis B vaccinations, and 4) new engineering controls required in the OSHA blood-borne disease standard that will provide further protection from injuries. As we have ventured through this process with our members, we have become convinced that the problem is serious and that there are methods currently available that can nearly eliminate the problem. However, there is little incentive for institutions to adopt these methods.

Surveys of our membership about the frequency of needlesticks and the health consequences have been very revealing. Our members' experience with needlesticks is reflected in much of the pioneering needlestick injury epidemiology reported by Janine Jagger, Ph.D. and her colleagues. Nursing and nursing students account for the lion's share of those reporting needlestick injuries, followed by laboratory technicians and other professional personnel in respiratory therapy. Our members also report that devices requiring assembly have been responsible for needlestick injuries.

Most reported needlestick injuries are associated with handling of the needle during or after disposal rather than during injections of medication or withdrawal of blood or body fluids.

One of our affiliates, the Wisconsin Federation of Nurses and Health Professionals, represents nurses and other health professionals in the large Milwaukee County Hospital, which has three separate facilities -- an acute care facility, a county jail facility and a mental health hospital. The health nurse serving employees there sees an average of ten cases of needlestick injuries every week. When we last interviewed her during the week of February 3, she had seen ten injuries in a two-day period. Activities associated with the injuries that were reported to her included: disposing of a needle in an over-filled needle box; retrieving a suture needle found on the floor; and drawing blood from a combative patient.

The recapping of needles accounts for a large share of injuries reported in this county institution, a practice Dr. Jagger and her colleagues cite as most apt to cause injury. In many instances, however, recapping cannot be avoided. Nurses who staff the Milwaukee County mental health facility offer a striking example. Puncture-proof containers cannot be installed in the rooms of these patients; needles in these containers could pose a serious risk for patients who are disoriented and unpredictable. To guard their

patients in these facilities, nurses feel that they must recap the needle before leaving the room to dispose of the needle. When recapping is done in these situations without special recapping devices, the risk of injury increases.

The Impact of Needlestick Injuries on the Work and Lives of Health Care Professionals

Needlestick injuries disrupt the professional and private lives of health care workers in distressing ways. The employee health nurse at Milwaukee County Hospital described one such recent case in graphic detail. A nurse working in the Milwaukee County jail health care facility was collecting a blood specimen from a prisoner who was known to be HIV positive. When she finished taking the specimen, she thought that she had disposed of the needle in a puncture-proof container in her specimen basket. Unfortunately, she had missed the puncture-proof box and the needle fell down to the bottom of the basket. When she returned to her office, she reached into the basket and was stuck by the prisoner's contaminated needle.

Filled with panic, she immediately reported to employee health services. Our employee health nurse told us that the nurse was so distraught she "couldn't hear me." The nurse was so anxious that she couldn't go back to work. Later her husband called the

employee health nurse in an effort to understand what had happened and the steps that should be taken.

This case is not unusual at Milwaukee General Hospital. In fact, the employee health nurse says that most workers who sustain a needlestick injury from a source known to be infected with HIV or hepatitis B usually can't go back to work for some time.

From a member's firsthand account, we can begin to understand many of the personal ramifications of a needlestick injury: A nurse who works in a coronary intensive care unit clamped her hand onto a 12-gauge, two-inch needle that was attached to a syringe full of blood. The needle was hidden under a stack of linens used as barriers during a procedure to introduce a catheter into the heart. The needle puncture was deep and painful. The nurse was extremely concerned and frightened. She spent two hours in the emergency room waiting to be evaluated after the needlestick, filling out forms and playing through a series of scenarios in her mind. What if I get infected with hepatitis or HIV? Who sees my confidential records? If I am infected, will I lose my job? Should I tell my family?

Unfortunately, no one was there to answer these questions. There was no protocol in place to provide counseling, suggestions for safe sex, or reassurance about where this information would be kept

and who would have access to it. Fortunately, this nurse is well and free of disease six months after this significant exposure.

What is important to note here, is that this nurse has had other needlestick injuries subsequent to the incident described and has not reported them for all the reasons described -- nor have her coworkers who also have had workplace exposure to patients' blood through needlestick injuries. Nor has the hospital responded to requests from these nurses to track and identify the procedures during which needlestick injuries occur most frequently and determine how they might modify these procedures to promote the safety of staff involved.

The Need for Action

The FNHP believes that there are several measures that can be taken now to end this human travesty. First and foremost, new needle technology should be introduced for nurses who face the threat of HIV, hepatitis and tuberculosis. New designs for safer needles eliminate recapping accidents and prevent injury if needles are accidentally misplaced or are projecting from over-filled needle boxes. The FNHP unsuccessfully introduced legislation in the state of Wisconsin that would have provided grants to hospitals to use and evaluate safe needle devices (please see attached). The State of New York Health Department implemented such a program when

similar legislation was passed in 1990. Such efforts are important, but they do not go far enough.

Second, the Food and Drug Administration can facilitate the introduction of safe and effective needle devices by developing stringent safety and performance standards. This action would remove the option for health care facilities to buy less expensive, substandard needles.

Third, the Occupational Safety and Health Administration will have an important part to play as it enforces its blood-borne disease standard. It can insist that health care facilities protect workers from exposure to blood and body fluids by using engineering controls (i.e., safe needle devices that will serve as fail-safe barriers to blood through needlesticks). OSHA can also insist that exposure control plans outline in detail the procedures that hold the greatest risk of needlestick injury. These procedure protocols should also designate the person responsible for the proper work practices during a procedure -- including disposal of needles and sharps. The recordkeeping of needlestick injuries as they relate to procedures will be especially important; this recordkeeping will help rank the relative risk of needlestick injuries from different procedures.

The OSHA standard should also be applied to persons who are not strictly hospital or health care facility employees, i.e. medical students, nursing students and others who may participate in procedures. There should be mandatory inservicing and training for these employees and their relative risk of exposure should also be assessed.

And last, the Centers for Disease Control should revise the 1987 guidelines for preventing exposure (CDC Recommendations for prevention of HIV transmission in health-care settings. MMWR 1987:36 (no. 2S)). These guidelines should emphasize the use of safe needle devices as the most effective method to prevent transmission of HIV and other blood-borne pathogens in a health care setting.

The FNHP hopes that these approaches will be adopted in a timely manner to insure that health care workers will be protected from potential work-related exposures and unnecessary stress and anxiety.

1 AN ACT to create 20.435 (1) (cj) and 143.09 of the statutes, relating to
 2 establishing a grant program in the department of health and social
 3 services to fund devices to prevent accidental puncture in health care
 4 settings, requiring health care providers to dispose of, in specific
 5 ways, certain devices used in health care settings, granting rule-
 6 making authority and making an appropriation.

Analysis by the Legislative Reference Bureau

This bill creates a grant program within the department of health and social services (DHSS) under which DHSS must allocate up to 5 grants of general purpose revenues in fiscal years 1991-92 and 1992-93 to applying hospitals or nursing homes that have significant numbers of patients with infections of HIV (human immunodeficiency virus, the virus that causes AIDS). The grants are to conduct projects to test the practicality and effectiveness of using, in health care settings, devices that are designed to prevent accidental puncture of the skin of health care providers. Health care devices that are so designed may be purchased with grant funds and used under the projects. DHSS must, under the bill, evaluate the program and report to the legislature on issues related to the effectiveness of the program by January 1, 1993. DHSS must also, under the bill, establish an 8-member technical advisory committee with which DHSS must consult prior to promulgating rules.

In addition, the bill requires health care providers, in the preparation for disposal of hypodermic syringes, needles and disposable units and certain other devices used in health care settings, to crush, break or otherwise render inoperable these devices. The bill permits DHSS to promulgate rules to specify procedures for this disposal.

For further information see the state and local fiscal estimate, which will be printed as an appendix to this bill.

The people of the state of Wisconsin, represented in senate and assembly,
do enact as follows:

SECTION 1. 20.005 (3) (schedule) of the statutes: at the appropriate place, insert the following amounts for the purposes indicated:

	<u>1991-92</u>	<u>1992-93</u>
<u>20.435 HEALTH AND SOCIAL SERVICES,</u>		
<u>DEPARTMENT OF</u>		
(1) HEALTH SERVICES PLANNING,		
REGULATION AND DELIVERY		
(cj) Health care device safety		
grants	GPR A	50,000 100,000

SECTION 2. 20.435 (1) (cj) of the statutes is created to read:

20.435 (1) (cj) Health care device safety grants. The amounts in the schedule for health care device safety grants under 1991 Wisconsin Act (this act), section 4 (1).

SECTION 3. 143.09 of the statutes is created to read:

143.09 DESTRUCTION OF DEVICES THAT MAY CAUSE ACCIDENTAL PUNCTURE.

(1) A health care provider, as defined in s. 146.81 (1), in the preparation for disposal of hypodermic syringes, needles and disposable units and other devices used in health care settings that may cause accidental puncture, shall crush, break or otherwise render inoperable the syringes, needles, disposable units and other devices.

(2) As necessary to protect public health, the department may promulgate rules to specify procedures in addition to those specified in sub. (1) for the preparation for disposal of hypodermic syringes, needles and disposable units and other devices used in health care settings that may cause accidental puncture. The procedures may include placement of the hypodermic syringes, needles and disposable units in leak-proof, puncture-resistant containers prior to disposal.

1 SECTION 4. NONSTATUTORY PROVISIONS; HEALTH AND SOCIAL SERVICES. (1)

2 HEALTH CARE DEVICE SAFETY GRANTS. (a) In this subsection:

3 1. "HIV" has the meaning given under section 146.025 (1) (b) of the
4 statutes.5 2. "HIV infection" has the meaning given under section 146.025 (1)
6 (c) of the statutes.7 3. "Hospital" has the meaning given under section 50.33 (2) of the
8 statutes.9 4. "Nursing home" has the meaning given under section 50.01 (3) of
10 the statutes.11 (b) From the appropriation under section 20.435 (1) (cj) of the
12 statutes, as created by this act, the department of health and social
13 services shall, after consulting with the technical advisory committee
14 established under subsection (2), allocate up to \$100,000 in each of
15 fiscal years 1991-92 and 1992-93 to provide up to 5 grants to applying
16 hospitals or nursing homes that have significant numbers of patients with
17 HIV infections, for projects to test the practicality and effectiveness of
18 using, in health care settings, devices that are designed to prevent
19 accidental puncture. Funds may be used for the purchase, at reasonable
20 cost, of hypodermic syringes, needles and related devices that are so
21 designed.22 (c) A hospital or nursing home that receives a grant under paragraph
23 (b) shall have established a staff committee that includes representatives
24 of labor and of management of the hospital or nursing home to implement
25 the grant. Criteria for membership for this committee shall be estab-
26 lished in rules that are promulgated by the department of health and
27 social services.

1 (d) The department of health and social services shall, after con-
2 sulting with the technical advisory committee established under subsection
3 (2), promulgate rules establishing the criteria and procedures for the
4 awarding of grants for projects under paragraph (b).

5 (e) The department of health and social services shall, after con-
6 sulting with the technical advisory committee established under subsection
7 (2), evaluate the program established under this subsection and shall
8 submit its findings and recommendations, by January 1, 1993, to the chief
9 clerk of each house of the legislature for distribution to the legislature
10 in the manner provided under section 13.172 (2) of the statutes. The
11 department shall examine, among other issues relating to the effectiveness
12 of the program, all of the following:

13 1. The impact of the use of devices that are designed to prevent
14 accidental puncture on the transmission of infectious disease and the
15 occurrence of accidental punctures in health care settings.

16 2. The availability and the cost, relative to other devices, of
17 devices that are designed to prevent accidental puncture.

18 3. The costs incurred and the savings realized by health care provi-
19 ders by the use in health care settings of devices designed to prevent
20 accidental puncture.

21 4. The practicality of using devices that are designed to prevent
22 accidental puncture, including the willingness of health care personnel to
23 use them.

24 5. The benefit, if any, of continued use of devices that are designed
25 to prevent accidental puncture.

26 (2) TECHNICAL ADVISORY COMMITTEE. The department of health and
27 social services shall establish an 8-member technical advisory committee
28 composed of 4 members who represent unions of health care workers and 4

1 members who are health care professionals whose work involves the control
2 of infections in hospitals or nursing homes, to assist and advise the
3 department in doing all of the following:

4 (a) Developing the rules required under subsection (1) (d).

5 (b) Reviewing and approving applications for grants under subsection
6 (1) (b).

7 (c) Evaluating the program established under subsection (1).

8 (3) GRANT AWARD RULES. The department of health and social services
9 shall submit proposed rules establishing criteria and procedures for the
10 awarding of grants under subsection (1) (b), as required under subsection
11 (1) (d), to the legislative council staff for review under section 227.15
12 (1) of the statutes no later than October 1, 1991.

13 (End)

IMS

INTERNATIONAL MEDICATION SYSTEMS, LIMITED

Randall J. Wall
President and Chief Executive Officer

January 6, 1991

The Honorable Ron Wyden, Chairman
Committee on Small Business
Subcommittee on Regulation,
Business Opportunities, and Energy
B-363 Rayburn House Office Building
Washington, D.C. 20515

Dear Congressman Wyden:

Thank you for the invitation to respond to your investigation of the needle stick issue in the Health Care Industry. International Medication Systems, Limited ("IMS") recognizes this very real and costly problem in health care and we applaud the efforts of you and your subcommittee in taking action on it.

Our company has also spent much time, effort and energy in the development and marketing of a safety system called the "Stick-Gard"TM protected needle to address this problem. Permit me to explain briefly the background of IMS and then to answer specifically those questions posed in your letter.

International Medication Systems, Limited is a manufacturer of generic injectable pharmaceuticals and is celebrating our fortieth year in business in 1992 (see attachment 1-A). Under new ownership since August of 1988, IMS was the innovator of the first pre-filled medication syringe, the "Min-i-Jet"^R. We subsequently licensed the design of the "Min-i-Jet"^R to two other health care manufacturers. The "Min-i-Jet"^R design continues today to be the predominant pre-filled medication syringe for emergency use.

IMS markets the "Min-i-Jet"^R system in the United States and in twenty six countries worldwide. In fact, IMS and the "Min-i-Jet"^R System enjoy an 80% market share in the United Kingdom. It is also the sanctioned emergency syringe on board every British Airline flight. We have been honored by NASA to have our products aboard Space Shuttle flights in April 1985 and June 1991.

In 1989, in response to the growing problem of needle sticks and the potential transmission of blood and airborne disease, IMS improved upon the original "Min-i-Jet"^R design by adding our patented "Stick-Gard"TM protected needle (Patent Number: Re. 33,617) to selected drugs in the "Min-i-Jet"^R system. We began with the most critical drugs, which are those being used most often in Cardio Pulmonary Resuscitation (CPR) i.e. Sodium Bicarbonate, Atropine, Calcium Chloride, Dextrose, Epinephrine.

The Honorable Ron Wyden
January 6, 1992
Page 2

The "Stick-Gard"TM protected needle is recessed into a plastic sheath to prevent touch exposure while allowing the needle to fit over all standard injection sites. We also manufacture and distribute the "Stick-Gard"TM protected needle as a "stand alone" item to be used in conjunction with secondary medication administration or attached to any syringe for I.V. injection (see attachment 2-A). With this background, let me address the specific points of your inquiry.

I. Regulatory Pathway/Roadblocks

The regulatory path through the FDA was straightforward with regard to the "Stick-Gard"TM improved "Min-i-Jet"^R for use with the five previously mentioned drugs. These drugs fall into the category B or "grandfathered" drug category and, as such, do not require an FDA approval. We did submit our 510K notification to allow marketing of the "Stick-Gard"TM needle as an alternative to the standard hypodermic needle and this marketing application was promptly received and granted.

FDA approval allowing inclusion of "Stick-Gard"TM on drugs regulated by the ANDA process has proven more complex and has not yet been completed. Supplements to ANDAs were submitted and the information exchange required for approval of this improvement is still in progress.

II. Structural/Procedural Roadblocks

Although the majority of the users of our "Stick-Gard"TM products: nurses, paramedics and emergency room personnel, recognize the unique advantages of the line, in most cases they do not make the final purchase decision. Because the "Stick-Gard"TM needle is attached to a pre-filled syringe containing medication, the "Min-i-Jet"^R with "Stick-Gard"TM is generally purchased under the pharmacy budget. Although these products will save the facility, at a minimum, the cost of a typical needle stick "work-up" (estimated at \$300-\$500 and as high as \$2500 if the Hepatitis B Vaccine is required), not to mention the much greater possible human consequence, the pharmacy typically is not willing to absorb through its budget any incremental cost for delivery of the drug with a safety device.

The Honorable Ron Wyden
January 6, 1992
Page 3

For example, IMS recently lost a bid to a major Hospital Buy Group in the Northeast, and received the comment: "We will not pay one penny more for your safety syringe". In this case the bid price for our line was five cents per syringe more than a competitor's drug without a safety needle. The total incremental cost to this buy group for our "Min-i-Jet"^R protected needle would have been approximately \$15,000 per year. This nominal cost would have virtually removed the needle stick risk for those drugs associated with our product.

Ironically it was in this same part of the country that Dr. Veronica Prego, M.D. contracted the Human Immunodeficiency Virus (HIV) through an accidental needle stick received from a contaminated hypodermic needle carelessly left in a bed by a hospital co-worker (see attachment 3A, 3B). Ultimately, Dr. Prego received over one million dollars in a settlement from New York City Health and Hospitals Corporation and two physicians over the incident. It is estimated that some 800,000 accidental needle sticks are reported by hospital personnel annually. Needle sticks are also estimated to be under-reported by approximately 75% (see attachment 4-A).

In addition to the incremental cost roadblock to introduction of a safety device, safety products like "Stick-Gard"TM typically must be brought before a committee and evaluated based on merits as well as balanced among the other issues before the committee. Usually there needs to be some one person or department to "champion" the product before the committee. This process, in the absence of outside pressure or incentive for a change in behavior, has led to a very slow, adoption of the line by many hospitals.

III. On Site Testing/Product Design

The "Stick-Gard"TM safety needle was first introduced to the market in late 1989. Subsequent to our introduction of this protected needle, we counseled with two of the most noted proponents of design technology and safety needles, Dr. June Fisher, PhD, San Francisco General and Dr. Janine Jagger, PhD, University of Virginia. Both of these professional women are noted for their preference for designing safer needles versus mandating rules for safety and both were complimentary about the "Stick-Gard"TM protected needle (see attachment 5-A, 5-B). Notwithstanding the previously mentioned cost obstacle, the current "Min-i-Jet"^R design has been extremely well received by the users of the products.

The Honorable Ron Wyden
January 6, 1992
Page 4

IV. Cost/Benefit

While unit sales nearly tripled from 1990 to 1991, the incremental units have been gained at considerable expense. Our standard cost for the product has increased approximately 30% while our prices have remained at parity with comparable non-safety products. Hospital resistance to payment for any safety increment has proven an impediment to more widespread sale of the product except where the safety enhanced product is priced at parity with the non-safety drug preparation.

Indeed, since IMS has the dominant patent on the "Stick-Gard"TM needle we were encouraged by leaders in the industry and supporters of our line to reduce our price. In light of the life protecting nature of the technology, it was argued that every incentive must be tried to introduce the product to the hospital. As the patent holder we agreed with the suggestion and, in July of 1990, reduced our individual "stand alone" unit price from \$.45 to \$.19, a fifty seven percent reduction. Our two competitors have not followed our lead and continue to market their products at approximately \$.45 per unit (see attachment 6-A, 6-B, 6-C). We also matched the price on our "Min-i-Jet"^R line with "Stick-Gard"TM with the price of the comparable non-safety product. Although unit sales are up significantly over last year, they still represent less than a 10% market share in the CPR market.

V. PRICE REDUCTION THROUGH VOLUME

Finally, it is difficult to provide a definitive answer to your last question concerning a possible price decrease following widespread adoption of safer needles. As mentioned, we have attempted to remove the price barrier on our line, pricing the product below the levels the technology, innovation and cost would appear to justify. The results have been much less than hoped for. Even mandated OSHA compliance memorandums like CPL 2-2.44B, (Section M-3A) and (Section M-d2) which outline new procedures for occupational exposure to the Hepatitis B Virus (HBV) and Human Immunodeficiency Virus (HIV), appear to have done little to encourage hospitals to spend incrementally on products which would remove the need for these costly OSHA guidelines.

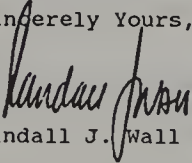
It appears that "better" pricing, alone, will neither increase acceptance nor provide inducement for the technological activity necessary to enhance safety. What appears to be missing is an incentive counterweight to cause the "up front" investment in the ultimately cost-saving products.

The Honorable Ron Wyden
January 6, 1992
Page 5

In my opinion, widespread acceptance and use of critical safety products like "Stick-Gard"TM will come only in a health care system disciplined to recognize and save costs, rather than shift them. To the extent that the management or reimbursement regime provides an incentive for each participant to save costs for the health care system as a whole, investment in safety, prevention and protection will be encouraged, individual health care will be enhanced, and the national bill for health care will be brought under control.

Thank you again for the opportunity to respond to your letter. If appropriate I would be happy to further discuss our experience with these issues and approaches to improving health care with you and the members of the subcommittee.

Sincerely Yours,



Randall J. Wall

RJW:sg
attachments



NATIONAL PHLEBOTOMY ASSOCIATION, INC.

2623 Bladensburg Road, N.E., Washington, D.C. 20018
(202) 636-4515

SUBMITTED TO: Subcommittee on Regulations, Business
Opportunities and Energy

SUBMITTED FROM: Diane C. Crawford, Chief Executive Officer,
NPA

SUBJECT: Hearing on Needlestick Injuries to Healthcare
Workers and Adoption of Safer Medical Devices
by the Healthcare Establishments.

DATE: February 7, 1992

A NON-PROFIT ASSOCIATION
ACCREDITING AGENCY

.....The Phlebotomist.....

The phlebotomist is a vital member of the clinical laboratory team, whose main function is to obtain patient's blood specimens by venipuncture and microcollection techniques, and to facilitate collection and transportation of other clinical laboratory specimens. Phlebotomists are employed throughout the health care system -- hospitals, neighborhoods health centers, medical group practices, HMO's, public health facilities, doctors offices and veterans hospitals.

The field of phlebotomy has greatly expanded in the past several years and the role of this integral member of the health care team has recently been brought into much sharper focus. The threat of AIDS, hepatitis, and risks to all segments of society from other infectious diseases has dramatically emphasized the need for quickly expanding training programs, while maintaining the highest possible standards of instruction and continuing education of these health care professionals.

Patient safety and quality assurance, which adheres to the most stringent professional standards, are essential at every echelon of the health care process. Society's continuing good health may very well depend on it. The phlebotomist has a direct effect on the overall quality of medical care.

.....The Nation.....

Through patience and diligence, NPA has put into place the phlebotomy training curriculum at universities, colleges and

hospitals across the country. NPA staff travels extensively to implement new programs and administer the certification examinations. The certification examination is also administered here in Washington for those who qualify to take the test from a carefully drawn criteria of on-the-job training.

But in terms of numbers, our work has just begun. There are approximately 7,700 hospitals in the United States, and nearly all of them are without an accredited phlebotomy training program. Of the estimated one quarter million practicing phlebotomist in America, only 6,000 have been certified by NPA.

The AIDS statistics and projections for the future have urgently changed priorities and timetables for many health related organizations. Raising public awareness, offering timely dissemination of available information, and expanding necessary programs are an essential and pressing priority.

.....The Community.....

The ongoing teaching program in Washington, D.C. has trained some 488 students and assisted in their placement in health care facilities and hospitals. Phlebotomy offers a professional status and skill which does not require an undergraduate degree. Minorities, single mothers and newly graduated high school students have been the primary recipient of highly trained, skilled professionals, and productive citizens as well.

Our training program offers the student four months of classroom instructions, and a two month internship at any of several local facilities.

The advancement of learning and education remains our very best hope of improving one generation over another. Upgrading the status of phlebotomists to a professional rank had been readily achieved during the past 14 years through the efforts of NPA right here in the Grater Washington Metropolitan community.

Have you ever wondered why you have a bruise after you have had blood drawn? It may very well be because of improper collection procedure.

Historically, on the job training has been the method used in various health disciplines including Phlebotomy. Prior to the inception of establishing the National Phlebotomy Association, the title of persons who drew blood was just blood drawers.

In 1978 the National Phlebotomy Association was established to:

1. Set standards for the field.
2. Set an accreditation mechanism.
3. Set a code of ethics.
4. Set certification.
5. Set curriculum guidelines.

NPA has been successful in accomplishing these goals throughout the country. However, we have just touched the tip of the needs for qualified individuals to perform in this profession.

There is still on the job training being done even here in the Nations Capitol. We estimate that less than 50% are certified or have received formal education in our local hospitals.

The Phlebotomist is exposed to blood borne pathogens continuously while performing collections. Needle stick injuries are a way of life with the Phlebotomist. Some institutions are still allowing the scooting or the recapping of needles. This is a very dangerous practice for Phlebotomist. There are many devises in the health care system that help to alleviate, or at least cut down this problem. But many institutions are not yet truly concerned with the all out safety of their employees.

With all of the sophisticated equipment laboratories have, and all of the technologist's education, those who run the analysis, it doesn't mean a thing if the persons who draw the blood doesn't understand the basic fundamentals of collection procedures.

Education is a must!! It needs priority in this field and must be put ahead of the procedure. Education in prevention must be the first step with providing quality health care, not only for the safety of the health care worker, but also for the safety of the patients. In giving proper education one should receive instructions on the proper use of a needle to prevent needle stick injury. The Center for Disease Control (CDC) estimates that 6,000-8,000 healthcare workers are infected with hepatitis B each year.

As a former supervisor who established the Team Concept for a phlebotomy team in a local institution here in Washington, D.C., I witnessed a patient go into cardiac arrest as a result of

mis-labeled specimen (blood work depends on the proper collection of specimen).

Having a needle like Bio-Plexus, Punctur-Guard blood collection needle, has proven to be the answer. After the collection of specimen the needle is dull thereby one will not be able to stick themselves. This has been the only product on the market which has not altered the Phlebotomist's normal procedure in collection of a blood specimen.

NPA not only requires education before practicing phlebotomy, but we also require our NPA Certified Phlebotomist to do the minimum of 18 contact hours per year to keep them abreast of what new procedures are taking place in this field.

We are committed to seeing the kind of safety procedures practiced in every healthcare institution, whether public, private, large or small, for-profit, non-profit, rich or poor, that will bring quality health care for all.

In closing, NPA will continue to promote education and certification to this well needed profession. We ask that this committee, along with other health care committees, join us in our efforts to mandate certification. We strongly encourage Congress to establish legislation to protect the health care worker from needlestick injury to be included in the legislation statement. Also any person drawing blood on a continual basis, and having the title of phlebotomist must have credentials. A certification from the National Phlebotomy Association is certainly one way of achieving that.



NORTH AMERICAN MEDICAL PRODUCTS, INC.

ROTTERDAM INDUSTRIAL PARK
BUILDING #501 - EAST ROAD
SCHENECTADY, NEW YORK 12306
(518) 356-8110 FAX (518) 356-8180

December 26, 1991

Congressman Ron Wyden
U.S. House of Representatives
Committee on Small Business
Subcommittee on Regulation
Business Opportunities, and Energy
B-363 Rayburn House Office Building
Washington, DC 20515

Dear Congressman Wyden:

I appreciate your writing to North American Medical Products about your investigations on this very crucial topic, and I hope the following information will be of service to your subcommittee in determining a course of action to follow.

As with any new technology, especially in the medical community, such as hospitals, clinics, health care centers and the like, effectiveness and cost become the two most predominant issues.

With regard to effectiveness, the structure of most hospitals is to present these new technologies to product review committees and then for formal evaluations upon committee approval. Even when these evaluations turn out positive, the administration or purchasing departments could put a hold on ordering these products due to budget restrains or concern over the perceived additional costs. They fail to realize that the cost of treating accidentally stuck healthcare workers, higher insurance premiums, as well as potential law suits are actually much higher than the protective devices such as ours. A good example is the insurance rates, which is illustrated in a letter sent to me by our product liability insurance agency, of which I have enclosed a copy.

Congressman Ron Wyden

December 26, 1991

- 2 -

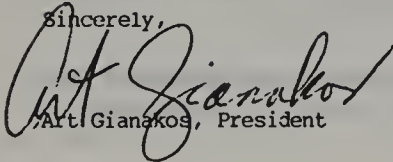
In regards to on-site testing of our device, we have been tested in hospitals, such as V.A. Hospitals in Miami, New England Deaconess, Boston and many other hospitals since our introduction in late September. The feedback has been very positive among the health care workers, and in our case, an appreciation of our product as the most versatile system in providing needle stick protection in most areas of the hospital. Since our prices are the most competitive in the industry, we have been well received on this issue as well. Regardless of this advantage, price of this system versus standard needle and syringe is still viewed as a much higher cost, although in the long term they will actually save.

Whenever there is new technology, adjustment to new techniques, justifiably or not, there will always be an excuse for some hospital personnel to avoid the final buying decisions, especially if higher costs are an issue. Each product on the market has its own idiosyncrasy and requires some adjustment. With regard to our product, we have developed a system which allows the hospital to use it in a variety of areas and thus reduce training confusion through standardization.

Finally, your question of if widespread adoption of safer needle technologies reduce the price? Absolutely!! In fact, the reductions could be anywhere from 15% to 30% depending on what unit volumes each company achieves. As for North American Medical Products, we are currently looking into robotics as a means to aid us in producing higher volumes at lower costs. The lower costs will eventually be passed along to the hospitals and other health facilities. Federal support in helping smaller businesses like ourselves obtain the necessary high speed production equipment would expedite these lower cost savings.

I hope the information I have given you will be helpful, and if I can be of any further assistance, you may telephone me at (800)488-6267.

Sincerely,


Art Gianakos, President

Incl.

AG/sm



January 9, 1992

United States House of Representatives
 Committee on Small Business
 Sub Committee on Regulation, Business Opportunities
 and Energy
 B - 363 Rayburn House Office Building
 Washington, DC 20515
 Attn: Matt Levinson c/o Ron Wyden, Chairman

Dear Mr. Chairman:

Your correspondence of December 11, 1991 addressed to Mr. Spiro Armenis, President and CEO of the Pascall Group, of which the Pascall Medical is a subsidiary, has been passed on to me for response.

For the record, the Pascall Group, has a number of working subsidiaries of which the Pascall Medical Corporation is one.

The President of the Pascall Medical Corporation is Elliot Kornberg, M.D., 1st VP of Operations and the official address of the Pascall Medical Corporation is:

Cape Royal Building , Suite 618
 1980 North Atlantic Ave.
 Cocoa Beach, FL 32931

I operate a residence office out of Bethesda, Maryland and am responsible for engineering sub-contract, and some marketing response.

Per your correspondence I offer the following in reply:

The Pascall Medical Corporation was established as a company dedicated primarily to the curtailing of the potential epidemic of infectious disease.

We have been involved in this endeavor and have been exposed to the field of infectious disease and its control for many years.

This exposure includes association with hospitals and infectious control committees, input from health professional organizations, allied working unions, health care professionals at all levels from hospital centers to private practice.

Mr. Ron Wyden
Jan. 9, 1992
Page 2

The corporation has developed a device called the "SPIVE" ("Special Purpose IV Entering") that virtually eliminates the risk of possible needlestick injuries at the site of the IV catheter from opening the device package, through use to ultimate disposal.

In a recent "Run Off" by a U.S. leading parenteral pre-filled syringe manufacturer, the SPIVE was selected as the front runner product to be included with their products for IV and implanted catheter administration.

Concerning the regulatory, structural and procedural roadblocks that prevent companies from successfully marketing and deploying safer needle technology, I present the following observations for your consideration.

- a.) Hospital Policy - It is my opinion, after years of discussion with health care administrators, that if faced with the decision to spend a few more cents and prevent a potential fatal needlestick, the hospital will go for the immediate cost savings.
- b.) Hospital Politics - Hospitals, centers, groups, whatever are usually aligned to one of the device manufacturers for a whole series of reasons, who, in general, or in concert with, prevent any new technology from being accepted, or more likely from being introduced to the hospitals new product introduction organization or committee.
- c.) General Institutional Ineptness - This includes governments (both national and local), hospitals, groups, plans that will risk a fatal infection like AIDS and have to payout \$160,000 for the maintenance of such disease rather than invest a couple of extra cents up front to prevent it.

Concerning the on-site testing and use of the "SPIVE" we have initially focused on a couple of hospitals and the feedback is very positive once the product is understood. We were especially impressed, that beside the IV catheter, the "SPIVE" was extremely beneficial for triple Lumen infusion not only for the nurse but also for the protection of the patient.

In terms of cost the "SPIVE" can be produced to the hospital direct for less than twenty cents in large quantities. The non shielded needle standard, through medical distributor ranges from seven cents to five cents. A average 300 bed hospital has approximately 200 IV related operations going on in a single day (1 change/12 hours).

"SPIVE" $\$.15 \times 365 \times 200 \times 2 = \$22,000$

Standard $\$.06 \times 365 \times 200 \times 2 = \$9,000$

Mr. Ron Wyden
Jan. 9, 1992
Page 3

So for \$13,000/year saving the hospital puts staff at risk, (from administration to disposal) and a potential cost to the system of \$160,000 (cited latest cost of AIDS patient care from diagnosis to death in New York City).

Concerning cost, all of the "No Stick" needle related devices that I am aware of cost more than a simple needle. In the case of some of the larger companies that are already net worked into hospitals the devices are highly overpriced, and complicated to operate. Some devices are sold to hospitals and never used because nurses find change hard. One particular no needle product increases infection rates and is an extremely expensive system. Because of large companies massive marketing effort and/or because the company is "locked in" with the hospital organizations the associated cost are acceptable.

The Pascall Medical "SPIVE" is one of the least expensive most straight forward to use device on the market for use with the implanted catheter infusion device. The "SPIVE" provides safety from the package to destruction. This level of protection reflects a lot of people in the "life of product" cycle. Most systems out there cannot make this claim.

There are many factors that can contribute to lower prices, but the most important are competition and volume. The problem with the hospital market in general, and with the drug/medical device industry in particular, competition is limited and almost hopeless with a new product and company start up. Without significant sales there is no volume, no additional production investment, no lower costs. There are a lot of good products out there that are caught in this circle.

In small quantities the Pascall Medical Corporation has to sell the "SPIVE" for \$.28 in quantities of 10,000 or less. We know that if we knew we could sell millions that the price could be reduced to at least \$.20 and with extra tooling and automation, lower.

The medical device market has to be one of the toughest markets to be involved in. Beside the market penetration a company is faced with federal regulation (which will be more demanding and in many ways needlessly more complicated in the next couple years), state regulations, seeking working capital, general business expenses, etc. - in any case, unless you have minority status - usually, no help from the government.

Sir, I have been associated with the drug/device industry for over 30 years. I have seen the political shortcoming of both industry and government during that time all at the expense of the patient and the system. I have seen extremely good ideas fail because of the system and bad products succeed, sometimes at the expense of the tax payer, always at the expense of the patient or health care worker.

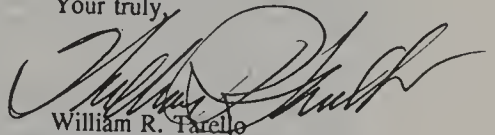
Mr. Ron Wyden
Jan. 9, 1992
Page 4

In this time of epidemic, and it is becoming a world wide epidemic your committee has the opportunity to make a difference at a stage where infection of health care workers, at the least, is not exactly out of control - these people must be protected.

There are all kinds of devices on the market, or trying to get on the market, that can do the job so that inflicted people can get care with minimum personal concern of the health care professional. Your job is to see to it that maximum protection is provided by using the best possible health care products benefiting professionals and the tax payer.

The nation and the world is faced with the biggest problem of our times. Make the difference. I would be glad to help.

Your truly,



William R. Tarello
VP Operation
4857 Battery Lane #304
Bethesda, MD 20814

cc: E. Kornberg MDP, President, Pascall Medical
J. Evanoff VP, Pascall Group, Inc.
S. Armenis, President, Pascall Group, Inc.

P.S. Please forward all correspondence to the Bethesda address or call or fax 301-986-0425.



7706 Crossroads Bldg
 Suite 201
 Brentwood, Tennessee 37027
 615/370-4242 Watts 1-800-BUY-RYAN
 January 6, 1992

Congressman Ron Wyden
 United States House of Representatives
 Committee on Small Business
 Subcommittee on Regulation,
 Business Opportunities and Energy
 B-363 Rayburn House Office Building
 Washington, D. C. 20515

Dear Congressman Wyden:

Thank you for your letter of December 11, 1991. I am glad to respond to your subcommittee's request and am pleased that such a serious issue is being studied.

My experience is that a hospital's reaction to protecting employees ranges from genuine concern to gross and conscious neglect. We have heard many hospital supervisors say they will not buy a safety product unless "someone makes them do it". While several forward-thinking institutions have initiated the use of safety products, many others have flatly refused to spend any extra for safety. In fact, in some hospitals, employees hesitate to report needlestick accidents for fear of losing their jobs.

"Universal precautions" simply do not exist. Even in "high risk" hospitals, safety products are used in only limited areas. One department in a hospital may initiate the change to a safety product within that department but the institution's safety committee will not approve it for general use.

Often safety products within an institution are allocated to the most influential departments rather than to those with the highest risk of exposure to contaminated needles. For example, a nursing floor usually receives such products before the blood laboratory where drawing blood from high risk patients is routine. Because of their lower "status" in the hospital "pecking order", phlebotomists are not granted the same concern by management as are nurses and the rest of the medical staff.

Ryan Medical currently sells three safety needle devices. These products have each been on the market for over a year. A published study comparing one of our products to current techniques showed an 82% reduction in accidental needlesticks. Common comments from our customers include, "my needlesticks have gone away" and, "I simply don't have needlesticks any more."

Congressman Ron Wyden

January 6, 1992
Page 2

One of our products also addresses the problems associated with the common practice of reusing blood tube holders. A recently published study shows that this practice is risky, to say the least. Yet virtually every institution reuses blood tube holders for reasons of economy and general nonchalance when it comes to the blood laboratory and the phlebotomists.

While we have developed a strong base of business for our safety products, there has been considerable resistance in many hospitals to using them because of their perceived higher cost and because of human resistance to change to anything that is new. Generally, a new product must be evaluated for at least 60 days to generate an acceptable comfort level with it. Less enlightened hospitals usually "cave in" to their medical staff long before such a study can be completed and the new product is not given a fair chance to succeed against an existing, less safe product.

The acceptance of ours and other safety products could be hastened by stringent enforcement by various regulatory agencies of the new OSHA Guidelines which were recently published. Publicity on institutions found in non-compliance will receive the immediate attention of other institutions. A more systematic means of reporting needlestick injuries to a governing agency would give much needed protection to healthcare workers who do not have strong representation from professional organizations or unions.

There is no common way in which hospitals judge the cost benefits of using safety products. Often the cost of lost time, employee testing and therapy after a needlestick accident, and overall insurance costs are considered part of general overhead and not allocated to a procedural cost. When true costs are properly allocated, the use of safety products are usually competitive with existing practices.

Having spent over twenty years in the medical products business, I have had significant experience with the Food and Drug Administration. Generally, I have been impressed by their professionalism and dedication. Of late, however, I am finding the FDA increasingly insensitive to the special needs of small companies such as Ryan. They expect that we can afford the time and the expense of extensive testing and lengthy delays they require for the introduction of new improved products. In the safety products area, better products are being developed every day which will further improve worker safety.

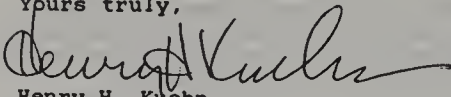
Congressman Ron Wyden

January 6, 1992
Page 3

We at Ryan have three such products ready to bring to market. We are prevented from doing so until we complete lengthy, expensive and, what I consider, unnecessary testing. We are being asked to provide new test data on materials, packaging and manufacturing process which have already been approved for other similar products.

Thank you, again, for your interest in what we at Ryan obviously consider a vitally important matter. While I am generally a believer in less government being better, I believe that the government has a legitimate increased roll in assuring health care workers a safe environment.

Yours truly,



Henry H. Kuehn
Chairman & CEO



SAFE TECH MEDICAL PRODUCTS, INC.

6731 ASHMORE DRIVE • HOUSTON, TEXAS 77069 • (713) 444-3581
RETRACTABLE SYRINGES

RE-TRAK™

U.S. Rep. Ron Wyden
House Subcommittee on Regulation,
Business Opportunities, and Energy
B 363 Rayburn
House Office Bldg.
Washington, D.C. 20515

Re: Retractable Syringe. Brochures, syringes

Dear Ron Wyden:

Although we have never met, I feel from reading the article in Hospital Employee Health about you that you and I are interested in the same values.

You were right when you said, "they have not put out the demand for safer needles."

It is almost as if more people have to die until they realize the issue.

I will get to the issue of this letter now. I have invented a retractable syringe, the Retrak. You give a shot and when the plunger goes down it locks with the head of the needle. Then all you do is draw the plunger back up and this draws the needle back up into the barrel. Next, you break off the plunger and cap the end of the syringe.

Now what you have in your hand is a sharps container. There is no chance what so ever of and needle stick. Also, not any fluid or blood can leak out because of the closed system. If a person is on the 8th floor of a hospital and has to give more than one shot, such as ten or twelve, and can not get to a sharps container, he will have no worries with the Retrak. He can put them in his pocket until he gets to a sharps container.

Next, we will talk about giving I.V.'s. I have invented a safety catheter for hooking up I.V.'s. I will explain the problem that is out there. When you tear open the needle catheter pack, you insert it into the arm and hold the catheter in the arm while you pull out the needle. Once this is done you have a needle in your hand. Sometimes at the scene of an accident they throw the needle on the ground while they are hooking the IV line to the catheter. In a hospital room they set it on the bed or night stand while they hook up the IV tube.

As you can see this is not good. I will tell you how mine works now. You push down a button on the tube and slide the needle and catheter out and into the arm. Next, you push the but-

**SAFE TECH MEDICAL PRODUCTS, INC.**

6731 ASHMORE DRIVE • HOUSTON, TEXAS 77069 • (713) 444-3581
RETRACTABLE SYRINGES

RE-TRAK™

ton back down and slide the needle back up in the tube and then cap it. As you can see we then have another sharps container until we get to one.

There is one other major fact. My products take up less space in the sharps container than Becton Dixon and Sherwood Medical. This is because when they slide their sleeves down it makes theres twice as long as mine. As you know for disposing medical waste less space is better.

I will send you some brochures, a sample prototype completed, and a copy of the patents. Please feel free to call or write me to know how you like my products.

Sincerely,

Michael Haining
Michael Haining

RE-TRAK[™]

BY

**SAFE TECH MEDICAL
PRODUCTS
INC.**

Another Product by the People
who believe
SAFETY COMES FIRST.

NEEDLE STICK
A Serious Problem

RE-TRAK[™]

The Way to Guard Against It

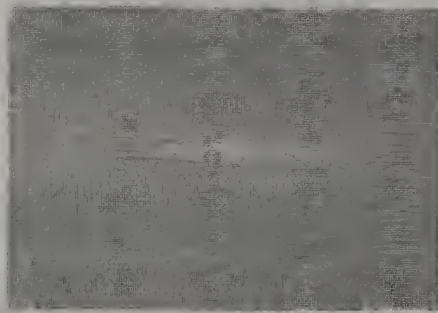
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•

(713) 444-3581

Remember, even if you are trained
against needle stick it still
can happen

So you must have a product that
can help
you protect yourself.



RE-TRAK[™]

SAFETY SYRINGE

SAFE TECH

**Medical Products
Inc.**[™]

SAFE TECH

Medical Products

Inc.TM

PROBLEMS

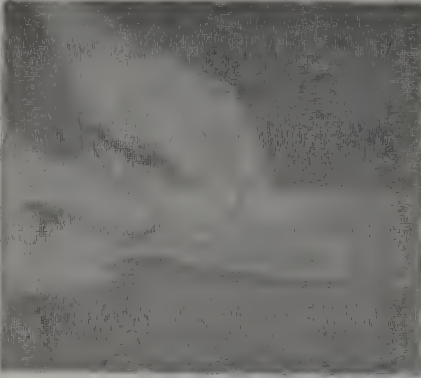
Today's Healthcare Professionals are fully aware that there is no cure for A.I.D.S.

When you are exposed to high-risk patients you are more likely to contract A.I.D.S., Hepatitis B, and Non-A, Non-B Hepatitis than any other group of working people.

Diseases are most commonly caused by needle stick injury. It is a danger to hospital technicians and even house keeping personnel, when each year approximately 7% of them are involved in a needle stick injury.

60% of needle sticks happen to nurses because they are the ones who usually give the injection in the hospital. It is very rare that a doctor gives an injection. He usually tells what has to be given and when to do so. This does not rule the doctor out because they do give injections when necessary.

1.



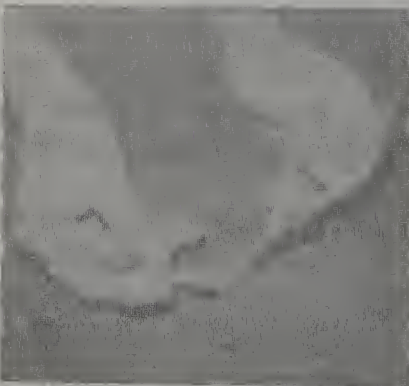
◀ Choose the syringe size you need. Make sure the package is unopened and undamaged. Syringes from damaged packages should not be used ever.

2.



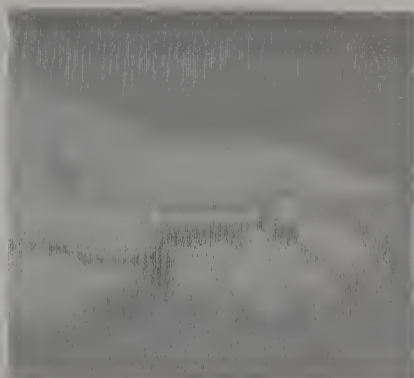
◀ Open package by pulling apart at the TAB at the top of the package.

3.



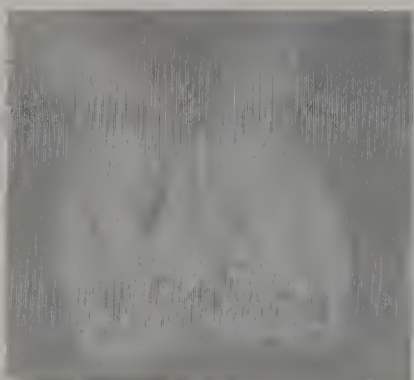
◀ Syringe comes ready to use. Just pull off needle cover carefully. Fill up with prescribed dosage.

4.



- ◀ Once injection is given, push plunger down until it locks and then draw up the plunger and needle into the barrel.

5.



- ◀ Then break off plunger in back of rubber.

6.



- ◀ Notice, there is not a way to get needle stick when the needle is drawn up and plunger is broken off.

7.



◀ Then dispose of everything into a disposable container.

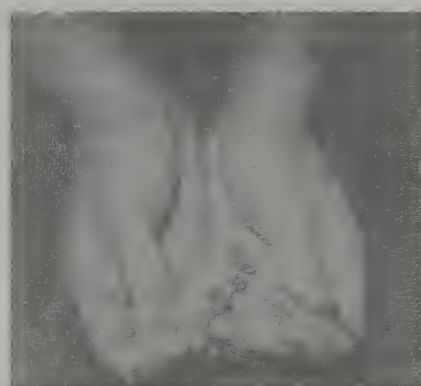
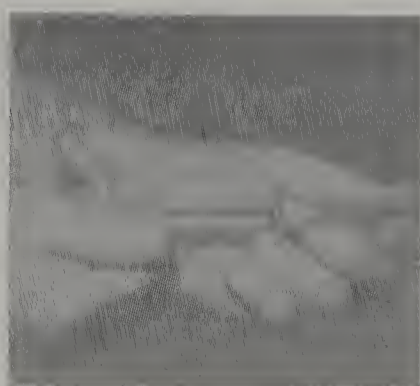
The expression "User Friendly" holds true in **RE-TRAK™**

It looks like a normal syringe but it is really not.

It protects you, the hospital worker, from needle stick.

It is so simple to use. Just fill with the normal dosage, give the injection, and press the plunger until it locks. Then pull up the plunger and just break it off and dispose of it.

Remember all you need is the edge against needle stick and that is what Safe Tech Medical is giving you with **RE-TRAK™**.



RE-TRAK[™]

SAFETY SYRINGE

SAFE TECH
Medical Products
Inc.[™]

•

• (713) 444-3581

David A. Low
President



Sherwood Medical
1915 Olive St.
St. Louis, MO 63103-1642
(314) 621-7788 Fax: (314) 241-4255

January 14, 1992

Mr. Ron Wyden
Chairman
United States House of Representatives
Subcommittee on Regulation
Business Opportunities and Energy
B-363 Rayburn House Office Building
Washington, D.C. 20515

Dear Mr. Wyden:

Thank you very much for your letter of December 11, 1991 addressing a number of issues that your subcommittee has investigated on the early detection and treatment of HIV and hepatitis B infection. I hope in this letter to answer most of the questions that you raised in that communication.

I would like to address the questions in the sequence in which you asked them and also provide a few other pertinent facts and comments regarding the whole area of healthcare worker safety and protection.

In reference to the major regulatory structural or procedural roadblocks that have delayed or prevented Sherwood from marketing and deploying safer needle technology, the most significant delay has occurred due to lack of a cohesive, structured and detailed regulatory program emanating either from OSHA or the CDC. Many hospitals have employed a "wait and see" attitude relative to the mandates that they will be required to comply with in the future. The medical industry has been uncertain whether this will take the form of training, product technology, or other mandates. Many hospitals and other healthcare institutions have been hesitant to make a firm commitment until such time as they could receive clear direction from the various governmental agencies. Hopefully, with the recent publication of the OSHA Bloodborne Pathogen Regulations in the Federal Register on December 6, 1991, some clear direction will be realized by the entire healthcare worker environment.

At the present time, Sherwood Medical has completed a series of on-site analyses of our 3cc Monoject Safety Syringe compared to a normal 3cc syringe. In recapping the results, the Monoject Safety Syringe was introduced to three hospitals that had not previously used this type of product and the incidence(s) of accidental needle sticks were greatly reduced.

Mr. Ron Wyden

-2-

January 14, 1992

In the 60 days prior to use of the Monoject Safety Syringe, needle sticks totalled 27 and during the 60 days that the Monoject Safety Syringe was under evaluation, needle sticks dropped to a total of 3; 1 of which was not a Monoject Safety Syringe product. This paper, when published in mid 1992, will confirm the significant reduction of needle sticks when the Safety Syringe was utilized. In addition, the Safety Syringe can be used safely with most I.V. Y-site systems on the market today. The only shortfalls of the current 3cc Safety Syringe offering is that it cannot be used for drawing arterial blood gas samples and may not fit all stopcocks.

The Monoject Safety Syringe has met with ever increasing acceptance at numerous hospitals throughout the United States. The feedback from the hospitals and healthcare facilities using this product has been uniformly positive. In addition, our standard rigid outer package has allowed for safe use and disposal of hypodermic syringes and needles since introduced over 30 years ago. This "System of Safety" packaging permits safe, quick and easy resheathing of used hypodermic needles in a one-handed operation affording the healthcare worker outstanding protection while complying with OSHA and CDC guidelines. Although we know that our recommendations meet these guidelines, there are some misunderstandings among clinical personnel.

In addition to the System of Safety packaging and the Monoject Safety Syringe, Sherwood Medical is one of the market leaders in the area of sharps containers and other waste disposal devices. This product offering has been expanded over the years to include a vast array of products to answer the requirements of healthcare facilities in more safely disposing of contaminated sharps.

Most everyone is aware of the cost pressures on Healthcare institutions today and thus the higher price of the Safety Syringe was initially an impediment. The significant reductions in needle stick injuries which Safety Syringe users have experienced, in conjunction with the newly enacted OSHA Bloodborne Pathogen Regulations, are beginning to increase the purchase of this product. In addition, current literature indicates that needle stick injury is costing hospitals and other healthcare sites an average of \$600 to \$1,000 to treat each initial injury. More and more healthcare facilities are comparing these costs to the incremental cost of a Safety Syringe and this also is facilitating the acceptance and use of these products. On average, the use of these products should result in the same, or less, cost to the hospital facility.

In response to your final question regarding the likelihood of reduced prices if widespread use of safety needle devices are adopted, there would be some economies of scale for the manufacturer and thus the price to the facilities would be somewhat less than the current price level.

Mr. Ron Wyden

-3-

January 14, 1992

Mr. Wyden, I have taken the liberty of enclosing literature on our MonojectTM Safety Syringe product line, as well as our new Value Added TrainingTM Program which has been designed to meet the training requirement of the new OSHA Bloodborne Pathogen Regulation.

I trust that I have answered your questions. Feel free to contact me directly if our organization may be of further assistance to you.

Thank you for the opportunity to communicate the manufacturer's point of view in this matter.

Sincerely,



David A. Low

DAL/dao

Enclosures



Sterimatic Medical Systems Ltd.

Abnosh, Cholford Hill, Stroud, Gloucestershire, GL6 8QN U.K. Tel: 0453 884944 Fax: 0453 886481

Congressman Ron Wyden
(Democrat of Oregon)
Chairman, Sub-Committee on Regulation, Business
Opportunities and Energy
115th Congress
B-63 Rayburn Building
WASHINGTON DC 20515
United States of America

6th February, 1992

Dear Congressman Wyden,

Congressional Hearing: Healthcare Worker Safety and
Needlestick Injuries

I have learnt today that you are the Chairman of a Congressional Hearing on the subject of 'Healthcare Worker Safety and Needlestick Injuries' to be held on 7th February, 1992.

Possibly the greatest occupational threat to healthcare workers is 'needlestick' injury: the accidental self inoculation of healthcare workers by needles contaminated with patient blood. Needlestick accidents are the most frequent and common occupational injuries (excepting back strain) to healthcare workers with an estimated 1 million such injuries per year in the US. Needlesticks are the major cause of occupationally acquired HIV and hepB infections by healthcare workers, resulting in 12,000 known hepB infections (250 deaths) and 200 known HIV injections in 1989.

I am writing to you because my company has been closely involved with the needlestick issue for the last three years, working closely with the UK Department of Health to minimise this serious hazard to healthcare workers.

It is widely accepted in the US and Europe that, with the growing risk of infection from patients carrying HIV, HBV and other infectious blood borne pathogens, healthcare workers must be given the most effective available protection from needlestick.

Extensive research and closely monitored trial programmes in US hospitals (in particular at Bellevue Hospital in NYC) have shown that procedural remedies (such as Universal Precautions) and the provision of post use needle containers at point of needle use make no difference to the number of needlestick injuries being sustained by healthcare workers.

52-372 427

Researchers and healthcare workers are agreed that the only effective remedy is to ensure that the needles themselves are designed to be safe to use. However there does not appear to be any regulatory or formal system to assess and approve the safety aspects of needle devices. A number of medical device manufacturers are currently presenting 'safety' needles with manually operated needle covering systems. The problems with these devices are that:

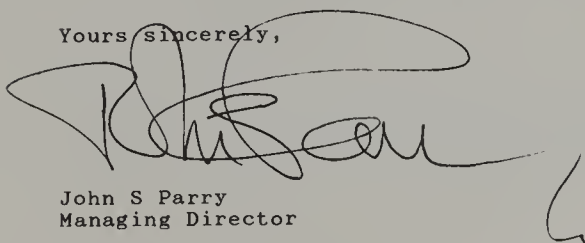
1. they are designed to operate only after needle use. They do not offer protection during medication when most needlestick accidents occur and,
2. they rely on a conscious operator procedure to protect the needle after use. Most needlestick accidents are caused by circumstances outside the operator's control (patient violence etc.) or by failure in existing operator procedures (distractions, tiredness, stress etc.). Some manually operated safety needle devices have been shown to increase the incidence of needlestick injury because the healthcare worker is required to perform a procedure involving their hand being close to an exposed, contaminated needle.

Extensive clinical experience, in the UK and US has shown that the only effective current remedy is a needle which is fully covered both during and after use, providing complete automatic operator protection from the moment of risk creation when the needle is introduced into the patient. This can be achieved by a needle offering automatic self sheathing in a failsafe, no operator procedure required mechanism. Following extensive trials conducted by the UK Department of Health, the Sterimatic Safety Needle is now formally recommended for use in UK hospitals by the Department and is in growing use across Europe. (I enclose a recent letter from the UK DoH).

Healthcare workers in the US, as in Europe, are continually exposed to unacceptable risks of infection because they are required to use dangerous equipment in hazardous conditions. The conditions will become increasingly hazardous in US hospitals with the increase in HIV positive patients. It requires a national commitment, as in the UK, to replace hazardous equipment, such as needles, with clinically tested and approved devices which offer proven protection from infection. Such protection is available now but will only reach the healthcare workers if and when US hospitals allocate the priority and dollar resources to access the proper equipment.

I would be grateful if you would include this letter in the public record of your hearing.

Yours sincerely,



John S Parry
Managing Director

Enclosures:

1. Sterimatic Safety Needle (SSN). Product literature
2. Letter from Baroness Hooper: Parliamentary Under Secretary of State for Health (Lords)



POH(6)2062/212

Dennis Skinner Esq MP

Richmond House

79 Whitehall

London SW1A 2NS

Telephone 071 210 3000

From the Parliamentary Under

Secretary of State for Health (Lords)

28 JAN 1992

Jan Dennis,

Thank you for your letter of 10 December 1991 to William Waldegrave enclosing one from your constituent Mr R J Hobson of 3 Main Road, Taddington about the risks of needle-stick injuries to Health Service workers.

Great importance is placed upon the safety of Health Service Personnel by the Department, and the avoidance of Needle-Stick injuries is one of the issues of particular concern.

As Mr Hobson stated, safety levels are greatly enhanced by the use of automatically re-sheathing needles, and the Department has stressed this point to health authorities. However, it is the responsibility of individual health authorities to decide which equipment to use.

Baroness Hooper

BARONESS HOOPER

Sterling Winthrop Inc.
 1100 Eye Street, NW
 Suite 1000
 Washington, DC 20004
 (202) 337-3400



VIA COURIER

January 10, 1992

Kathleen M. Whyte
 Vice President
 Government and Industry Affairs

The Honorable Ron Wyden, Chairman
 Subcommittee on Regulation,
 Business Opportunities, and Energy
 Committee on Small Business
 U.S. House of Representatives
 Washington, D.C. 20515

Dear Congressman Wyden:

Thank you for the opportunity to present our views on this most important issue regarding needle technology as a method for curtailing the rapid spread of infectious blood-borne diseases. Sterling Winthrop Inc. through its affiliate Sanofi Winthrop Pharmaceuticals, currently offers a sterile pre-filled unit dose injection system under its Carpuject® (sterile cartridge needle unit) brand name. Carpuject products allow for easy loading, efficient medication administration, and safe disposal of the used cartridge needle into an environmentally safe container. In addition, although recapping is a discouraged practice, if it occurs, the rigid plastic needle guard provides extra protection against needle sticks.

One of the major roadblocks preventing us from further increasing the use of Carpuject is a general reluctance on the part of some hospital pharmacists to purchase safer products because their acquisition cost is higher than individually purchased amps and vials. The Carpuject product line is offered at competitive prices that reflect the manufacturing and development costs of this safer technology. Other factors that influence the availability of pre-filled safety syringes have been the slow regulatory review of line extensions and the protection afforded to other manufacturers' patent property.

Sterling continues to research and develop improvements for the safe delivery of injectable drugs. While it is difficult to determine whether widespread adoption of safer needle technologies would significantly reduce their cost, it is certain that it would create a safer working environment for all healthcare workers.

Sincerely,

Kathleen M. Whyte

Kathleen M. Whyte



301 Catrell • Howell, MI 48843 • (517) 546-5400

January 6, 1992

Mr. Ron Wyden, Oregon, Chairman
102nd Congress
US House of Representatives
Committee on Small Business
Subcommittee on Regulation, Business Opportunities, and Energy
B-363 Rayburn House Office Building
Washington, D.C. 20515

Dear Mr. Wyden:

Thank you for your December 11, 1991 request for information on the marketing of needlestick prevention devices. We respond to your questions in the order presented in your letter.

I. We have had good success in marketing our Kleen Needle system since its introduction in the fall of 1990.

- A. The major regulatory roadblocks have been the absence of mandatory requirements for the use of protective devices such as ours. CDC has had Universal Precautions guidelines for some years. OSHA has had a blood-borne pathogen control recommendation in place in 1990 and 1991. However, neither of the above had the force of law. The March 6, 1992 Effective date of OSHA's 1910.1030 Blood-borne Pathogens, if strictly enforced, should encourage wider spread use.
- B. Structurally, perhaps the biggest obstacle is gaining approval of an institutions' New Products Evaluation Committee. It can usually be done, but such devices represent change of habits, procedures, protocols, etc. of many hospital departments - the result can be significant time delays - even before the hospital's financial approval or disapproval is considered.
- C. Procedurally from a clinical standpoint, the biggest challenge is in service retraining of the hospital staff. Also, a frequent issue that surfaces is interface incompatibility of devices from different manufacturers.

II. As regards on-site testing, before a sale at a specific hospital, we usually have the hospital purchase a small trial usage order to confirm product acceptance before facility wide implementation. We have done this hundreds of times with our

Tri-State Hospital Supply
Page 2

Kleen Needle system. The result has been enthusiastic endorsement by nurses and a steadily increasing sales volume for Tri-State Hospital Supply Corp. Use of our devices have eliminated countless accidental needlesticks and, based on statistics of infections per needlestick, have likely prevented the transmission of HIV and HBV a number of times in the last fifteen months.

- III. In terms of cost, the protective needle devices are more expensive, if only a side-by-side comparison of old and new technology is made. But if the social, and actual costs of treating hepatitis and aids infected patients and healthcare workers is factored into the analysis the incremental cost of protective devices is going to look like a pittance when viewed from the perspective of the five years hence. In sum - short term they are more expensive; long term the overall cost savings in healthcare will exceed preventative device costs many, many times over.

Yes, higher cost is sometimes an impediment to the hospital. A hospital must balance the short term cost increase against whatever its current fiscal crunch is. Sometimes, the long term view is missed.

- IV. Yes, widespread adoption of safer needle technologies will ultimately reduce the price of the products. As unit volumes go up, more elaborate automation equipment can be justified. As competing healthcare manufactures do this, some or all of the reduced costs will be reflected in lower prices to hospitals as a result of the competitive market process. For example, many of the protective needle products now on the market are made on 2,4,8, or 16 cavity molds. When this technology is at full volume, such parts will be produced on 64 or 128 cavity molds - as today's exposed hypodermic needles typically are - at much lower unit costs.

Sincerely,



Don Propp
New Product Development

cc: Tom Archipley, President
Mike Obsitnik, Vice President

Special Report and Product Review

Reprinted From **Health Devices** Published by **ECRI**
 Restricted use see back cover

Injectors, Medication/Vaccine [12-504]; Syringes, Cartridge [16-585]; Catheters, Intravenous, Peripheral [10-727]; Catheter Introducers [10-678]; Intravenous Medication Connectors [17-501]; Catheter Injection Ports [16-858]; Blood Collection Tube Adapters [17-814]; Syringes, Hypodermic [13-940], Insulin [13-941], Tuberculin [13-945]; Needle Guards [17-812]; Needles, Blood Collecting [12-736], Hypodermic [12-745], Intravenous [12-748]; Needle-Recapping Devices [17-813]

Needlestick-Prevention Devices

According to the Centers for Disease Control (CDC), needlestick injuries account for 80% of reported occupational HIV (human immunodeficiency virus) exposures, which could lead to AIDS (acquired immunodeficiency syndrome). Although the fear of contracting AIDS has overshadowed the concern about acquiring the hepatitis B virus (HBV) through an accidental needlestick, the risk of acquiring — and dying from — HBV is actually much greater: CDC reports a 6% to 30% chance of acquiring hepatitis B from a percutaneous injury with an HBV-contaminated needle. Physicians, nurses, clinical laboratory technicians, pharmacy personnel, housekeeping staff, and waste handlers — all healthcare workers who may be exposed to patients' blood or body fluids — are at risk.

The October 19, 1987, Joint Advisory Note of the Departments of Labor and Health and Human Services states, "Whenever possible, engineering controls should be used as the primary method to reduce worker exposure to harmful substances. The preferred approach . . . is to use, to the fullest extent feasible, intrinsically safe substances, procedures, or devices." Given this statement and the incidence of occupational AIDS and hepatitis B transmissions, the best way to reduce the risk of needlestick injury may be to use a needlestick-prevention device or to eliminate the needle from the procedure entirely.

Many manufacturers are marketing products that reduce the risk of needlestick injuries, and the number of different products available is rapidly increasing. In this Special Report and Product Review, we provide general background information and guidance on the need for and use of needlestick-prevention devices, as well as reviews of 26 such products from 22 manufacturers, divided into eight different Product Groups. Also, the Discussion and Recommendations section provides guidance on selecting products for four main clinical uses and includes a discussion of cost analysis, including a cost comparison model based on ECRI's new Computer-Aided Health Devices™ (CAHD™) CAHDModel™ system. (See pages 149 to 153 for more information on CAHD and CAHDModels.)

Finally, we would like to thank CDC for its review of this report.

The Risk and Prevention of Needlestick-Transmitted Infections

RISK ASSESSMENT

Accidental needlesticks occur frequently, posing a serious risk of transmitting fatal or chronic diseases to a wide range of healthcare workers. As one physician noted, "Rarely a day goes by in any large hospital where a needlestick incident is not reported" (Roberts JR 1987). Needlesticks have long been associated with transmitting both bacterial infections and viral infections, such as hepatitis B; now, they also serve as the agent of transmission of the human immunodeficiency virus (HIV), which causes acquired immunodeficiency syndrome (AIDS). This threat has spurred the development of the preventive devices examined and discussed in the pages that follow.

Sources of Risk

A number of clinical procedures and housekeeping activities carry an increased risk of needlestick injuries, including (1) disposing of or recapping used needles, (2) administering parenteral medications, (3) drawing

blood, and (4) collecting linens and trash. In one study of 316 reported needlesticks (conducted before the use of needle disposal systems ["sharps" containers]), disposing of needles accounted for 24% of injuries; recapping needles, 12%; administering parenteral medications, 21%; drawing blood, 17%; and collecting linens and trash, 16% (McCormick and Maki 1981). In another study of 286 reported needlesticks, drawing blood constituted the highest risk, 20.6%; followed by recapping or corking needles, 18.2%; handling trash, 16.1%; and giving injections or infusions, 15.4%. Interestingly, injuries from needles poking out of overfilled needle disposal containers — which are designed to protect workers from accidental sticks — constituted 8.4% of the total injuries (Neuberger et al. 1984).

According to another study of 1,201 healthcare workers with blood exposures, 80% of which were due to needlesticks, 37% may have been prevented if recommended infection control precautions had been fol-

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Special Report and Product Review

lowed (Marcus and CDC Cooperative Needlestick Surveillance Group 1988). The exposures were caused by recapping needles by hand, 17%; improperly disposing of sharps, 14%; and exposing open wounds to sources of contamination, 6%. The remaining 63% of the exposures involved manipulating intravenous (IV), phlebotomy, or arterial needles (36%) during an invasive procedure (8%), autopsy (2%), or other procedure (17%).

Accidental needlesticks have been associated with the transmission of AIDS, hepatitis (B and C), and many other viral, rickettsial, bacterial, fungal, and parasitic infections. In addition, personnel face a significant risk of injury from accidental sticks with needles contaminated by toxic antineoplastic drugs and immunotherapeutic agents. Although it is difficult to predict the exact degree of risk of acquiring a specific disease from an accidental needlestick because of pathogenicity dose, host susceptibility, and other factors, some information on the risks of acquiring AIDS and hepatitis B, the two diseases most commonly associated with needlestick injuries, is available.

• Needlesticks and AIDS

Thus far, the available evidence indicates that healthcare workers face a small — yet nonetheless real — chance of acquiring HIV through accidental sticks with needles contaminated with the virus. According to two studies, the percentage of HIV seroconversions per known HIV exposures was 0.43% and 0.41%, respectively (Marcus and CDC Cooperative Needlestick Surveillance Group 1988; Gerberding et al. 1988). And prospective studies in the United Kingdom and Canada reported that 220 healthcare workers exposed to parenteral, mucous membrane, or cutaneous blood or body fluids in patients infected with HIV showed no evidence of HIV transmission (McEvoy et al. 1987; Health and Welfare Canada 1987).

Two other studies assessed the risk of occupational transmission of HIV infection for healthcare workers. One study, conducted by the National Institutes of Health (NIH), tested 1,344 healthcare workers with 170 documented needlestick exposures and 345 mucous membrane exposures to the blood or other body fluids of HIV-infected patients and reported only 1 HIV seroconversion as of December 1989 (Henderson et al. 1990). The other study, done at the University of California, included 212 healthcare workers that had documented 625 needlestick injuries or mucous-membrane exposures as of March 15, 1988, and again only 1 seroconversion following a needlestick was reported (Gerberding et al. 1987). In addition, in the study reported above of 1,201 healthcare workers who had been exposed to blood as of July 31, 1988, the serum of 963

healthcare workers (860 of whom had received a needlestick or cut from a sharp instrument) was tested for HIV at least 180 days after exposure, and only 4 tested positive for HIV after exposure to a needlestick injury (Marcus and CDC Cooperative Needlestick Surveillance Group 1988).

Based on the landmark studies of Marcus, Henderson, and Gerberding cited above, as well as other studies, Henderson concludes that, "The risk of HIV-1 transmission with a percutaneous exposure to blood from an HIV-1-infected patient is approximately 0.3% per exposure." As of June 1990, only 19 to 24 HIV seroconversions were reported in the U.S., but many more may not have been verified by or known to CDC.

According to Janine Jagger, M.P.H., Ph.D., of the University of Virginia, who gave a presentation at the Sixth International Conference on AIDS in San Francisco on June 22, 1990, current technology has the potential to prevent 85% to 90% of needlesticks; based on an estimated 800,000 needlesticks per year: "If 2% of hospital patients are HIV seropositive, and consequently 2% of needlesticks are HIV contaminated, then 64 healthcare workers will seroconvert per year, and 57 of those seroconversions would be preventable with technology that exists today."

• Needlesticks and Hepatitis B

Although the opinions of healthcare experts vary about the risk of acquiring hepatitis B from an accidental stick with a needle contaminated by the virus, experts agree that the risk is *significantly* greater than that of acquiring HIV through a needlestick. According to the Hepatitis Branch of CDC, an estimated 12,000 healthcare workers exposed to blood become infected by HBV each year — 500 to 600 are hospitalized, 700 to 1,200 become HBV carriers, and approximately 250 die from acute or chronic consequences (CDC 1989). In contrast to the relatively small number of HIV transmissions, the annual incidence of infection with hepatitis B among laboratory staff, surgeons, physicians, and nurses is estimated at 37, 25, 11, and 4 per 100,000, respectively (Finch 1987). Chronic sequelae of HBV infection include both cirrhosis and at least 80% of all primary liver cancers. Hepatitis B has also been known to be transmitted from a mother to her fetus.

OSHA requires that hospitals offer hepatitis B vaccines free of charge to employees who are at substantial risk of direct contact with patients' blood and body fluids. Available hepatitis vaccines provide over 90% protection against hepatitis B for seven or more years; however, many healthcare workers still do not receive the vaccine, taking action only when a needlestick injury actually occurs.

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Special Report and Product Review

RISK MANAGEMENT

The risks associated with needlesticks underscore the importance of implementing effective risk management efforts that reduce exposure and the likelihood of transmission. First and foremost, healthcare workers at high or moderate risk should receive the hepatitis B vaccine, all healthcare workers should follow universal precautions (as outlined in NCCLS Document M29-T), and healthcare workers who sustain needlestick injuries should report them in accordance with hospital policies and procedures. In addition, hospitals should enhance worker safety by implementing policies and procedures, discussed in detail below, to prevent needlestick injuries. Failure to take protective measures, such as those recommended by CDC and enforced by OSHA (Instruction CPL 2-2.44B), could lead to increased employee injuries and the losses associated with such injuries. In addition, it could result in the imposition of citations and civil penalties by OSHA as a violation of its general duty clause. These recommendations (e.g., for sharps disposal) are also likely to be introduced in litigation as the standard of care for hospitals regarding prevention of AIDS or other transmissible diseases to healthcare workers.

Reporting

Just as healthcare workers often fail to be vaccinated, they often fail to report needlestick injuries. In a 1986 survey of 1,473 nursing and medical personnel employed in two hospitals, 33.6% of the respondents had one or more needlesticks, but did not report the incident (Jackson, Dechairo, and Gardner 1986). A recent survey in a U.S. Air Force base hospital found that more than one-third of the 334 healthcare workers who had received a needlestick or other means of blood exposure did not report the injury through hospital reporting channels; the reasons given were lack of time or the feeling that it was not dangerous (*Hospital Infection Control*, August 1990).

As of June 1989, a 24-hour needlestick hotline has been available at San Francisco General Hospital. The hotline provides immediate counseling and helps San Francisco General's healthcare workers determine the necessary prophylactic care. Also, if zidovudine (Retrovir®) is recommended immediately, it can be obtained through the hotline program. At the Sixth Annual International Conference on AIDS, it was reported that this service had prompted a 69% increase in the number of needlestick injuries reported at the hospital.

OSHA requires that "any needlestick requiring medical treatment (e.g., gamma globulin, hepatitis B immune globulin, hepatitis B vaccine, etc.) shall be recorded. In addition, since this type of treatment is considered abso-

lutely necessary . . . such an injury cannot be considered minor" (Instruction CPL 2-2.44B). Hospitals should strongly emphasize the importance of reporting a needlestick injury as soon as possible to maximize the effects of postexposure follow-up.

Hospital Liability and Costs

In addition to their ethical concerns for employee well-being, hospitals face concerns about accidental needlesticks posing significant liability and costs. Hospital employees who contract an infection as the result of a needlestick are entitled to Worker's Compensation benefits. Because Worker's Compensation is a no-fault system, benefits are available regardless of whether the employee followed safety rules and preventive practices. Although Worker's Compensation is generally an exclusive remedy, some commentators have suggested that an employee might nevertheless be able, in some jurisdictions, to sue the hospital in tort on the theory that it intentionally created a hazardous work environment by disregarding proper safety precautions. And physicians and other nonemployees are not bound by Worker's Compensation and could bring a tort suit against the hospital. For example, in a highly publicized lawsuit, Veronica Prego, M.D., contended that she acquired AIDS from an accidental needlestick at a New York City hospital where she had been an unpaid extern. The hospital settled the case for \$1.3 million. The potential for hospital liability is likely to increase with safer product availability, especially if the hospital fails to provide such devices.

The combined costs of employee time lost, laboratory testing, case investigation, and, if necessary, treatment stemming from a needlestick injury can be significant. In one hospital study, conducted over a 47-month period from 1975 to 1979, the incidence of accidental needlestick injuries was as high as 81.8/1,000 employees; the 316 needlesticks reported constituted one-third of all work-related injuries in the hospital during this period (McCormick and Maki 1981). In addition, 1,053 incidents of needlestick injuries were reported to the Worker's Compensation insurance of the University of Texas Medical Branch Hospitals in Galveston between November 1, 1984, and January 31, 1989; 61.6% of the incidents involved nurses, and 6.7% involved physicians (Mansour 1990).

OSHA may impose fines up to \$70,000 (for repeated violations) on hospitals that fail to take measures to protect workers, giving hospitals a further incentive to abide by CDC recommendations. If hospital policies are at variance with CDC recommendations, documented — and defensible — reasons should be provided for the hospital's policies.

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Special Report and Product Review

Methods of Prevention

Several methods of reducing the incidence of needlestick injuries are available. These include (1) increased education and training of all hospital personnel who come into contact with used — and thus potentially contaminated — needles, (2) a proposed OSHA ban on traditional recapping by the two-handed technique, (3) appropriate use of needle and syringe disposal containers, and (4) the use of needlestick-prevention devices.

• Education and Training

Proper education of employees about the importance of following universal precautions; using approved disposal methods, including recommended impervious disposal containers; prompt emptying of disposal containers before they overflow; and using preventive devices are essential elements of a program to minimize needlestick occurrences. However, education, while indispensable, is not a panacea for needlestick prevention.

Several surveys of nursing and medical personnel have revealed that they do not perceive education as an effective means of reducing needlestick injuries. In one article, the authors note that "most respondents reported some knowledge of proper needle disposal techniques and perceived lack of knowledge as the least important reason for needlestick injuries" (Jackson, Dechairo, and Gardner 1986). Similarly, in another survey, nurses felt that "talks and information on preventing needle injuries and awards to individual nurses with good safety records" were the least effective solutions to needlestick injuries (Feldman 1986). Instead, nurses viewed such practical measures as more frequent inspections and more frequent emptying of disposal containers as the best way to reduce injuries.

Despite these views, education is of documented benefit. The significantly higher rates of needlestick injuries for part-time employees, who "may be less familiar with the routines utilized for needle disposal and also less available for in-service education" (Neuberger et al. 1984), attest to the value of education. Educational efforts should be directed toward physicians, nursing personnel (including RNs, who in one study showed twice as many needlesticks as LPNs), clinical laboratory technicians, and housekeeping staff; special efforts should be made to educate part-time personnel and employees on all three shifts, as well as personnel with less than one year's experience, because these groups appear to be at greater risk for needlesticks (Neuberger et al. 1984). Educating healthcare workers about the importance of receiving the hepatitis B vaccine, as discussed above, is also important.

An effective in-service educational program to prevent needlestick injuries should:

- Explain the hazards and risks associated with bloodborne pathogens, using the latest literature available.
- Stress hospital policies on needle use and disposal.
- Describe the steps for reporting and following up on a needlestick injury, should one occur.
- Provide the necessary training on any specific needlestick-prevention devices used.

The effectiveness of training should be assessed, for example, by questioning personnel on their understanding and knowledge, observing actual practice (handling and disposal), and monitoring the frequency of incidents. Training techniques, programs, and frequency should be modified as appropriate.

• The Needle-Recapping Controversy

CDC, Environmental Protection Agency (EPA), and Joint Commission on Accreditation of Healthcare Organizations (JCAHO) all recommend that needles *not* be recapped by the traditional two-handed technique. In its latest proposed recommendations on prevention of HIV transmission in healthcare settings, OSHA states: "Needles shall not be recapped [by the traditional two-handed technique], purposely bent or broken by hand, removed from disposable syringes, or otherwise manipulated by hand. Resheathing instruments, self-sheathing needles, or forceps shall be used to prevent recapping needles by hand" (Instruction CPL 2-2.44B).

In support of this position, numerous studies show recapping to be the cause of a significant portion of all needlestick injuries (Edmond et al. 1988). According to a recent study performed at four large teaching hospitals, the percentage of injuries resulting from needle recapping was greater than 25%, and exceeded 50% in four instances (Becker et al. 1990). The reasons for recapping were listed as inadequate knowledge (i.e., the misperception that recapping is a way to avoid needlesticks), concerns about personal risk, forgetfulness, and being too busy to follow universal precautions.

Some researchers and practitioners favor recapping with a wide-mouth needlecap, a one-handed scoop technique, or a recapping device. Proponents of recapping argue that while, in theory, disposing of uncapped needles into permanently sealable containers sounds like an ideal solution to the needlestick problem, in actuality this technique poses additional problems — not all needles are properly disposed of, and needles stuffed into overfilled containers may still be dangerous. Although the traditional two-handed recapping technique may be hazardous, handling an exposed contaminated needle is no safer.

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Special Report and Product Review

As a result, recapping proponents claim, "over one-half of needle injuries, particularly those occurring during disposal, are now inflicted away from the bedside by uncapped needles, many of which probably could have been capped at the bedside" (Sumner 1985). One danger of these so-called "downstream" injuries, they argue, is that victims have no idea whether the needles they have been stuck with are contaminated, whereas those who recap needles at the bedside using safer recapping devices "are in a good position to permanently neutralize the needle and to seek appropriate treatment if they do suffer a stick" (Sumner 1985).

Problems with recapping underscore the need for proper training. In one recent study, the rate of needle recapping used with venipuncture and for percutaneous medication injections fell from 61% to 16%. In this 12-month period, an educational program was developed that reported the rate of needle recapping to employees (Ribner and Ribner 1990). In addition to such preventive measures as thorough education and training and the use of preventive devices, proper disposal techniques must be used.

• Sharps Disposal

CDC stresses that disposal containers for needles should be located as close as possible to the point of use, presumably at the bedside in all patients' rooms.* However, such a plan poses significant operational problems:

To provide a box at the bedside, with a lock to affix it to the wall, requires personnel time and a regular maintenance schedule. This may be relatively easy in an ICU where boxes at each bedside are within a single confined area, the number of needles handled is great, and boxes often require emptying or changing on at least a daily basis. It is more difficult to implement in patient rooms that are widely dispersed throughout a multifloor building or several buildings, where needles are handled less frequently and at variable rates per room. These factors increase the difficulty in establishing a routine maintenance schedule because the need to empty or change boxes would vary from room to room and floor to floor (Jackson, Dechairo, and Gardner 1986).

Similar problems are posed by affixing a needle disposal box to the nursing medication cart. Ideally, medication carts should be brought to the patient's bedside. In practice, however, many medication carts remain in the nursing station or hallway while nurses carry individual medications to patients by hand, a situation that "leaves the nurse at one end of the hall with a used needle and the dilemma of how to get it

safely back to the disposal box in the nursing station" (Jackson, Dechairo, and Gardner 1986).

Hospitals purchasing a needle disposal system should make sure it is properly labeled and stands out as an infectious waste disposal container. Some disposal systems available are visually aesthetic and may be confused as a noninfectious unit (e.g., a towel dispenser).

While any needle disposal system is likely to have important limitations, it is an essential component of any needlestick-prevention program. In addition to ensuring that the system is easy to use and that containers are sturdy, it is important that the disposal container be located in all patients' rooms and other areas where needles are used and that a maintenance schedule that precludes overfills be established. Staff responsible for replacing containers should be clearly identified (e.g., nursing, housekeeping), and a mechanism for recognizing, reporting, and correcting any container hazards that may arise should be in place.

• Preventive Devices on the Market

In the following section, we review 26 products from 22 manufacturers that represent some of the devices currently being marketed for needlestick prevention. We have divided the products into eight different Product Groups based on their intended use:

1. Needleless medication/vaccine injectors
2. Prefilled medication systems
3. IV starters with catheters
4. IV medication connectors
5. Blood collection systems
6. Disposable syringes
7. Needle guards
8. Needle-recapping devices

We reviewed products that are marketed as aids in reducing needlestick risks and that were provided to us for inclusion in this study; additional products may also be available. These devices were assessed for their ease of use and effectiveness in preventing needlesticks in various applications. Although we have included list prices for all devices and accessories, the actual selling prices may be substantially lower; thus, we have included guidance on performing a cost analysis in "Analyzing Costs Associated with Needlesticks and Preventive Devices" in the Discussion and Recommendations section. Also in this section, we address which of the Product Groups afford the greatest protection for four main applications in "Selecting Needlestick-Prevention Devices for Four Clinical Applications."

* For further information on waste disposal containers, see ECRI's *Product Comparison Systems*.

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Special Report and Product Review

Product Reviews

In this section, we examine 26 products from 22 manufacturers, categorized into eight Product Groups. Although we describe the general effectiveness of the Product Groups and comment on the individual devices in this section, readers should also refer to the Discussion and Recommendations section, where we provide guidance on which Product Groups are appropriate for four main clinical applications, before making purchasing decisions. (Products are not shown to scale.)



Product Group 1: Needleless Medication/Vaccine Injectors

General description: This group consists of gas-pressurized, needleless injectors that replace a syringe and needle. Current systems can deliver intramuscular (IM) or subcutaneous injections, primarily vaccines. Medication injectors intended for home use are not included in this review.

General effectiveness: The single medication/vaccine injector we examined is effective in preventing needlesticks; however, it has limited applications. It may be useful in a large clinic that is administering large numbers of vaccinations.

BIOJECT BIOJECTOR®
Bioject Inc. [108133]
7620 S.W. Bridgeport Rd.
Portland, OR 97224
(503) 639-7221

Description and use: The Biojector is a reusable vaccination injector that uses pressurized CO₂. Users can fill disposable single-dose Bioject ampules with different solutions. The injector delivers a fixed IM or subcutaneous unit dose of 0.5 mL.

According to the manufacturer, the Biojector is currently being used with the DPT (diphtheria, pertussis, tetanus), influenza, tetanus, MMR (measles, mumps, rubella), yellow fever, and typhoid fever vaccines; it can also administer medications such as narcotics, analgesics, anticoagulants, vitamins, antibiotics, and hormones, but in only 0.5 mL doses.

List prices:

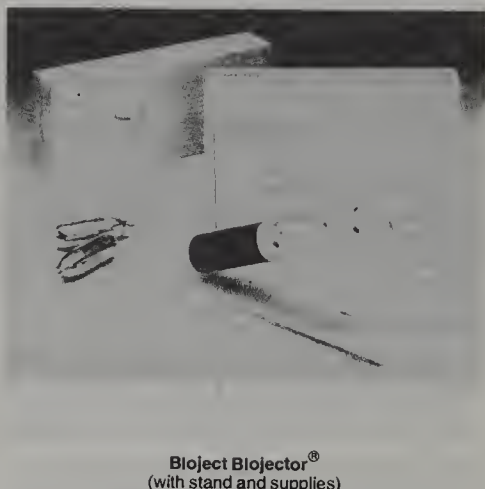
Cost/unit: \$475, Biojector

Additional costs/item:

\$0.40, CO₂ cartridge (10 to 20 injections/cartridge)

\$0.99, sterile single-dose disposable drug ampule

Comments: This product reduces cross contamination from needlesticks when administering IM or subcutaneous injections. A needle is still necessary to draw



Bioject Biojector®
(with stand and supplies)

medication into the ampules, although it poses little risk of infection because it is not used for injections. The manufacturer states that prefilled variable-volume ampules will be available in the near future that will eliminate the need for a needle and allow the unit to be used for additional medications.



Product Group 2: Prefilled Medication Systems

General description: These systems, which are marketed as preventive devices by the manufacturers, were designed as convenient methods of administering medications and minimizing errors by supplying pre-measured unit doses. Current products consist of a reusable cartridge holder and prefilled medication cartridge with a needle and are intended to be dropped into a nearby needle disposal container after use.

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Special Report and Product Review

General effectiveness: None of the systems we examined effectively reduce the risk of needlesticks and are not recommended as needlestick-prevention devices. Prefilled medication systems are no safer than using a needle and syringe — the user is at risk from the exposed needle after use until it is disposed of. This especially affects those healthcare workers that do not have a disposal container nearby because of the risks of transporting the exposed needle and cartridge to a container. These products do eliminate the need for a needle for drawing medications into the syringe, but this procedure does not pose an infection risk.

WINTHROP PHARMACEUTICALS CARPUJECT®
Winthrop Pharmaceuticals
Div. Sterling Drug Inc. (104392)
90 Park Ave.
New York, NY 10016
(212) 907-2525; (800) 446-6267

Description and use: The Carpuject is available with a variety of medications and solutions. Users dispose of the cartridge by unscrewing the plunger, opening the blue cam lock, and releasing the cartridge directly into a disposal unit. No needle protection is provided after the cap is removed.

List prices:

Cost/unit: No charge for Carpuject holder

Additional costs/item: \$0.40 to \$1.00 for the different cartridges

Comments: This system does not reduce the risk of needlesticks. If the disposal system is not located nearby, users may recap the needle or unscrew the cartridge and manually dispose of it, increasing the risk of needlesticks. Also, the reusable holders may be misplaced.

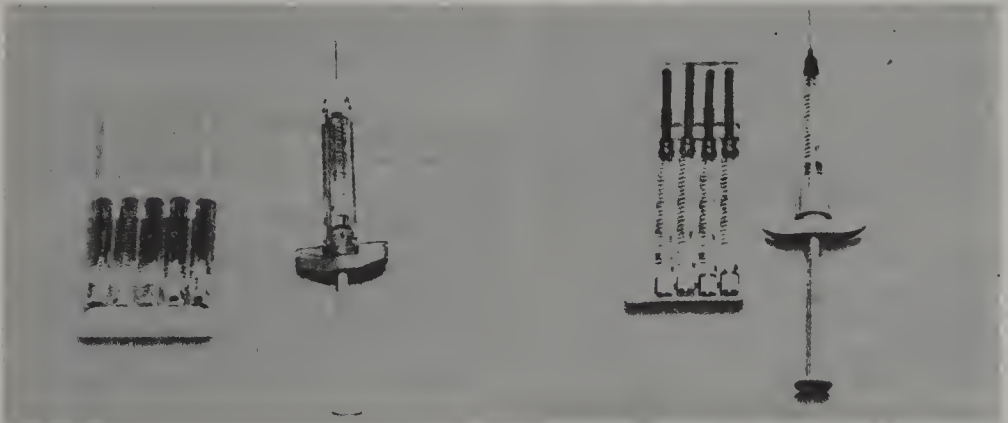
WYETH-AYERST TUBEX®
Wyeth-Ayerst Laboratories (101864)
P.O. Box 8299
Philadelphia, PA 19101
(215) 688-4400; (800) 424-8800

Description and use: The Tubex is also a needle cartridge system. Wyeth-Ayerst has disposable cartridges for a variety of medications and solutions. The design of the reusable holder is slightly different from that of the Winthrop Carpuject system. The cartridge is unscrewed from the holder and dropped vertically into a disposal container; the needle cannot be recapped. No needle protection is provided from the time the cap is removed to the time the cartridge is discarded.

List prices:

Cost/unit: No charge for Tubex holder

Additional costs/item (examples only; additional cartridges are available):



Winthrop Pharmaceuticals Carpuject®
(prefilled medication cartridges [left] and holder and cartridge set up for use)

Wyeth-Ayerst Tubex®
(prefilled medication cartridges [left] and holder and cartridge set up for use)

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Special Report and Product Review

\$0.52 to \$0.83, heparin lock flush solution
 \$0.55 to \$0.66, morphine
 \$0.63 to \$0.69, codeine
 \$0.73 to \$0.81, hydromorphone

Comments: This system does not reduce the risk of needlesticks. If the disposal system is mounted too high or is a horizontal-drop container, users may unscrew the cartridge and manually dispose of it, increasing the risk of needlesticks. Also, the reusable holders may be misplaced.

❖ ❖ ❖

Product Group 3: IV Starters with Catheters

General description: We examined three catheters and one needle infusion set used to administer IV therapy and draw or administer blood. These devices may incorporate a heparin lock for intermittent ("push") medication therapy.

General effectiveness: The four devices we reviewed provide some safety when removing the introducer needle from the catheter or the infusion set needle from the arm. These products represent different needlestick-prevention designs, three of which appear to effectively reduce the risk of needlesticks: the Critikon ProtectIV™ can be used to replace many common catheters, the Menlo Care Landmark® catheter is expensive and is primarily intended for intermediate-term and special applications, and the Ryan Medical Shamrock™ is appropriate only for short-term use and where its metal needle will not be a problem. The Deseret Intima™ reduces some of the risks of needlestick, but can still pose a significant hazard — for example, if misplaced in linens. Thus, hospitals will need to consider specific clinical needs and determine whether these or other products are appropriate.

CRITIKON PROTECTIV™

Critikon Inc.
 A Johnson & Johnson Co. [101346]
 4110 George Rd.
 P.O. Box 31800
 Tampa, FL 33631-3800
 (813) 887-2000; (800) 237-2033

Description and use: The ProtectIV is an IV catheter with a built-in guard that covers and locks over the introducer needle as it is withdrawn from the vein. The catheter is available with different needle sizes (14 G to 24 G).



Critikon ProtectIV™
 (before use [left] and after use showing protected
 needle for disposal [center] and catheter)

List price:

Cost/unit: \$2.50, ProtectIV catheter

Comments: This product appears to be easy to use and to reduce the risk of needlesticks when IV therapy is started. However, like any such catheter, this device terminates in a Luer hub without a septum (or extension tubing), which exposes the user to the patient's blood. The manufacturer recommends using digital pressure above the catheter tip during the procedure, quickly connecting the IV set, and using gloves to minimize blood contact.

DESERET MEDICAL INTIMA™

Deseret Medical Inc.
 Becton Dickinson and Co. [101750]
 9450 S. State St.
 Sandy, UT 84070
 (801) 255-6851; (800) 453-4538

Description and use: The Intima is an IV catheter with an introducer needle attached to a stylet. After the catheter is in place, the needle-stylet assembly is removed through an injection adapter (which reduces blood leakage), exposing the needle. The Intima is available with or without a Y-site and with different needle sizes.

List prices:

Cost/unit:

\$2.30, Intima IV catheter

\$2.30, Intima IV catheter with Y-site

(PRN injection adapter included with catheter)

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Special Report and Product Review



Deseret Medical Intima™
(before use [left] and after use showing needle stylet
for disposal [center] and catheter)

Comments: The flimsy stylet on this product reduces the risk of needlesticks, although contact with the needle is possible while holding the stylet. Of even greater concern, the stylet could be left in the linen, and nursing or housekeeping staff could become injured by the needle end. Bright, visible color on the stylet might help minimize, but not eliminate, this risk. Also, if the stylet is removed improperly, blood could splash in the user's eye. The stylet may also be more difficult to aim into a disposal container and may pop out of the top more easily.

MENLO CARE LANDMARK®
Menlo Care Inc. [107575]
1350 Willow Rd.
Menlo Park, CA 94025
(415) 325-2500; (800) 752-8900

Description and use: The Landmark catheter is an over-the-needle device that is inserted in the antecubital fossa area and advanced up to six inches until the tip is in an upper-arm vessel. After the catheter is placed in the arm, the needle stylet is removed and locked into a protective case.

Applications include selected chemotherapies, hydration therapy, antibiotic therapies, blood delivery, and pain management. The catheter is made of Aquavene, which softens to reduce vein trauma and subsequent complications. This catheter is designed to be used for intermediate-term therapies (typically 10 days to several weeks) and is therefore introduced through a sterile procedure. It may be used as an



Menlo Care Landmark®
(before use [left] and after use showing protected
needle for disposal [center] and catheter)

alternative to a central line or multiple peripheral sticks for some applications. The manufacturer suggests that this catheter can be used by home infusion therapy patients (especially those with AIDS or cystic fibrosis); cardiac, pediatric, obstetric, and orthopedic patients; and some oncology patients.

List price:

Cost/unit: \$33 per Landmark catheter in case volume

Comments: This product reduces the risk of needlesticks, but is useful for only very specific applications.

RYAN MEDICAL SHAMROCK™
Ryan Medical Inc. [108525]
Suite 201
7106 Crossroads Blvd.
Brentwood, TN 37027
(615) 370-4242

Description and use: The Shamrock safety-winged, butterfly-needle infusion set provides a safety shield over the needle when it is removed from the vein. A visual indicator appears when the needle is locked inside the shield, which also produces an audible click.

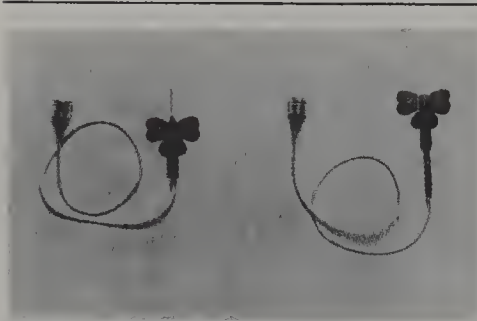
List price:

Cost/unit: \$0.58, (21 G, 23 G, or 25 G) Shamrock needle

Comments: This device reduces the risk of needlesticks. However, the nurses we spoke with were concerned that a steel needle is not as effective as a flexible catheter in minimizing trauma to the patient's vein. The manufacturer states that this device is intended for short-term IV therapy, for which this may not be as great a concern, or IV therapy for children. It is considerably less expensive than the catheters in this group.

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Special Report and Product Review



Ryan Medical Shamrock™
(before use [left] and after use)

♦ ♦ ♦

Product Group 4: IV Medication Connectors

General description: These devices are intended to eliminate an exposed needle after administering medications through an IV delivery system or catheter. They may also be used for collecting blood through an IV line into a syringe or possibly a blood collection tube adapter (see Product Group 5). Several of the products we examined have a needle recessed in a plastic covering that can be inserted into a Y-site; the other end of the product has a Luer fitting for connecting a syringe or another infusion set. Three such products, the Baxter Needle*Lock™, IMS Stick-Gard™, and the Tri-State Kleen-Needle®, provide a simple protective needle system for connecting to most standard septum-terminated Y-sites. Two other manufacturers, Burrton Medical and ICU Medical, will soon introduce comparable products.

Other products in this group are similar, but are intended for use with their own specific injection adapters (e.g., those used as a heparin lock) that can be purchased separately or as part of the manufacturer's extension set; these additional components must be considered in the cost. Two manufacturers also have valves that can be used in place of a stopcock or injection adapter, and one manufacturer has a needle-free device that uses a plastic cannula.

These other systems are designed for special applications or may require special or additional products. Some of these devices used at a Y-site for administer-

ing drugs must be positioned relatively close to the catheter site; users should judge whether this will be inconvenient. None of these devices are designed for IM use, and, except as noted, they require a needle to draw up the medication. Users must carefully assess the cost, compatibility with existing systems, and benefits of these products.

General effectiveness: All of the IV medication connectors reduce the risk of needlesticks when a standard needle would otherwise be used to give intermittent IV or piggyback medications; however, the clinical usefulness depends on the hospital's needs and existing products. Because a needle is used only for withdrawing medication from a vial and not for injecting the patient, there is little risk of infection; however, users may be tempted to use this needle for injection.

A concern with these products is how often they need to be replaced to maintain asepsis. Depending on the way the product is designed and packaged, it may need to be replaced either every time a medication is given or possibly not until an IV set is changed. (This also affects cost per use). Also, some concern may exist about the degree of asepsis protection as devices are connected and disconnected. For example, Luer connectors cannot be effectively wiped with alcohol, a common procedure with septum interfaces. Placing a cap over exposed Luer ports may help maintain an aseptic interface.

Most of these products have not had sufficient clinical trials to determine whether they pose any increased risk of patient infection. The Infection Control Committee and users should therefore review the use of these devices before implementing them and should monitor sepsis frequency. Again, the most effective and safe way of using these products should be determined and then monitored to confirm proper usage.

**BAXTER HEALTHCARE INTERLINK™
IV ACCESS SYSTEM**
Baxter Healthcare Corp.
I.V. Systems Div. [106390]
1425 Lake Cook Rd.
Deerfield, IL 60015
(708) 940-5000

Description and use: The Interlink IV Access System, which is designed to replace the traditional needle and injection adapter, consists of two mating components: a special injection adapter connected to the Luer fitting of the catheter or extension set and a blunt plastic cannula that inserts into the special septum of the injection adapter. The cannula is available for syringes and IV sets (lever or threaded-lock connector) and prefilled syringes (heparin lock flush or sodium chloride). Also available is

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Special Report and Product Review



Baxter Healthcare Interlink™ IV Access System
(multidose drug vial adapter [arrow], blunt cannula [in circle, left], injection adapter [in circle, right], and different types of cannulas [bottom]: threaded lock [left] and lever lock)

a multidose drug vial adapter to avoid having to use a needle when drawing the drug into the syringe.

List prices:

Cost/unit:

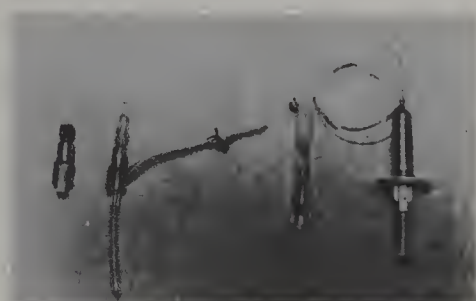
- \$1.50, Interlink injection adapter (replaced with each catheter or set change)
- \$0.25, blunt cannula
- \$0.45, lever-lock cannula
- \$0.50, threaded-lock cannula
- \$2.50, drug vial adapter

Comments: This system eliminates the need for needles to draw up medications or solutions from multidose drug vials. The manufacturer states that it will offer a cannula for single-dose drug vial access sometime this year. The blunt cannula can be used with only the manufacturer's injection adapter. This adapter can be purchased separately or as part of the manufacturer's special extension sets with a Y-site. The full benefits of this product are achieved only when the entire system is used. Users should evaluate compatibility with existing IV products (e.g., extension sets) and carefully assess total system needs, costs, and benefits.

BAXTER HEALTHCARE NEEDLE*LOCK™

Baxter Healthcare Corp.
I.V. Systems Div. [106390]
1425 Lake Cook Rd.
Deerfield, IL 60015
(708) 940-5000

Description and use: The Needle*Lock consists of a needle recessed in a plastic housing with a Luer connector on one end that can connect to any Luer connec-



Baxter Healthcare Needle*Lock™
(device as packaged [left] and attached to a Y-site [center] and a secondary medication set)

tion (e.g., syringe, IV set). The needle housing at the other end of the device has a plastic hook that allows the Needle*Lock device to be secured on the Y-site. This device is available alone or as part of a secondary medication or IV set.

List prices:

Cost/unit:

- \$0.50, Needle*Lock (18 G or 20 G)
- \$3.78, secondary medication set with Needle*Lock (18 G)
- \$4.25, IV set with Needle*Lock (20 G)

Comments: This device may be useful for piggybacking medications, because it provides a secure connection without taping. It cannot be secured directly to a catheter except at a Y-site. If this product is compatible with existing IV sets, it may be less expensive than some of the other devices in this group.

BURRON MEDICAL SAFSITE™

Burron Medical Inc.
Div. B. Braun of America Co. [101098]
824 12th Ave.
Bethlehem, PA 18018
(215) 691-5400; (800) 523-9695

Description and use: The Safsite is a reflux valve with a Luer connection at both ends. It opens when any standard Luer taper is connected and closes when the taper is disconnected. The valve is designed to replace an injection adapter and is compatible with standard IV sets. The Safsite can be purchased separately or with different extension sets. It is available with a Luer-lock replacement cap. A Luer adapter that can fit on a Winthrop Pharmaceuticals Carpuject cartridge is

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Special Report and Product Review



Burrion Medical Safsite™

(reflux valve as packaged [left], T-port extension set with reflux valve attached to a T-port extension with a dead-end cap on valve [center], and reflux valve attached to an extension set as it might be used)

also available; this adapter replaces the Carpuject needle provided and fits onto the Safsite.

List prices:

Cost/unit:

- \$2.30, Safsite reflux valve with small-bore T-port extension set, male Luer-slip fitting
- \$2.20, Safsite reflux valve with 6" small-bore extension set, male Luer-slip fitting
- \$1.07, Safsite reflux valve adapter
- \$0.25, Carpuject cartridge Luer adapter

Comments: Some users may be concerned about environmental pathogens entering this system; however, the Safsite valve is available with a standard dead-end cap similar to port covers on a stopcock. This device can be used as an injection adapter, in place of a stopcock, or with the manufacturer's extension sets. It is not compatible with the injection adapters on existing IV sets.

Burrion plans to offer its new Safsite Access Pin, which is designed to convert a Y-site on an administration set to a needle-free access site.

ICU MEDICAL CLICK LOCK™

ICU Medical Inc. [105658]
142 Technology Dr.
Irvine, CA 92718
(714) 753-1599; (800) 824-7890

Description and use: The Click Lock consists of a needle recessed in a plastic housing with a Luer connector on one end that can connect to any Luer connection (e.g., syringe, IV set).



ICU Medical Click Lock™

(as packaged [bottom] and set up for use)

List prices:

Cost/unit:

- \$1.60, Click Lock (with 18 G, 20 G, 21 G, or 23 G needle)
- \$0.48, injection adapter
- \$0.07, replacement needle (18 G, 20 G, 21 G, or 23 G)

Comments: This product is not compatible with some catheters unless the manufacturer's adapter is used, and it requires the manufacturer's adapter for piggybacking medications. A catheter or IV set with a Y-site or injection adapter may not be compatible with the Click Lock because the needle may not fit in the injection site or adapter. However, the manufacturer states that a new version will soon be available that ensures a secure and locked connection to injection ports on all standard IV administration sets with a Y-site. The manufacturer claims that the needles on the Click Lock can be replaced, which reduces costs. However, the risk of infection should be evaluated by the hospital before considering this procedure.

IMS STICK-GARD™

International Medication Systems (IMS) Ltd. [104648]
1886 Santa Anita Ave.
South El Monte, CA 91733
(818) 442-6757; (800) 423-4136

Description and use: The Stick-Gard consists of a needle recessed in a plastic housing with a Luer connector on one end that can connect to any Luer connection (e.g., syringe, IV set). This device can also be used with selected IMS MIN-1-JET prefilled syringes and is available in 18 G or 20 G needles.

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Special Report and Product Review



IMSStick-Gard™
(as packaged [left] and set up for use)

List price:

Cost/unit: \$0.19, Stick-Gard

Comments: This product appears to work well for intermittent medications with IV sets or catheters and may be less expensive than some of the other devices in this group.

L & W TECHNOLOGY SAFEPORT™
L & W Technology Inc. [108520]
P.O. Box 69392
Los Angeles, CA 90069
(213) 275-7464; (800) 648-5920

Description and use: The Safeport injection site, which is used in place of an injection adapter, works like an automatic stopcock. This product is designed with an antibackflow and anti-air embolism valve. It has Luer-lock connections at each end, and a syringe or IV line can be locked onto the Safeport for continuous or intermittent use. It is available as a single-, double-, or triple-port manifold. The double- and triple-port manifolds have an in-line check valve in the main flow channel, allowing injections to be given without needing to manually pinch off the IV line.

List prices:

Cost/unit:

\$2.35, single-port Safsite

\$4.70, double-port Safsite

\$6.95, triple-port Safsite

Comments: This device is designed to be used for ICU or anesthesia patients who may need to have a syringe left on the IV line while being closely supervised for intermittent medication doses (e.g., during slow administration of a drug such as Dilantin), for multiple simultaneous injections, or for other applications in which a stopcock would normally be used. When this



L & W Technology Safaport™
(single port as packaged [left] and triple port with syringes attached as it might be used)

device is used in place of a stopcock, it does not reduce the risk of needlesticks, because a needle would not normally be used. (When a stopcock is used, it has a Luer connection so that a syringe would be hooked up directly; no needle is needed.) Users may be concerned about environmental pathogens entering the system; however, the Safeport is capped with a standard dead-end cap similar to port covers on a stopcock. This is a relatively expensive device and is intended for specialized use, and the user must ensure that Luer connections are present at the site of application.

PASCALL MEDICAL SPIVE
Pascall Medical Corp. [108524]
Sulta 618
Cape Royal Bldg.
1980 N. Atlantic Ave.
Cocoa Beach, FL 32931
(407) 784-4448; (800) 848-3036



Pascall Medical SPIVE
(attached to syringe)

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Special Report and Product Review

Description and use: The SPIVE (Special Purpose IV Entering) device is a recessed needle device designed to be used only at a catheter with an injection adapter to administer intermittent medications. The device terminates in a Luer connector. The product is packaged as it is used, without a cap over the needle (see photo).

List price:

Cost/use: \$0.45, SPIVE

Comments: This product has just recently been introduced. It is not intended for use at a Y-site or for nursery applications.

RYAN MEDICAL SAF-T CLIK® IV IN-LINE CONNECTOR
Ryan Medical Inc. [108525]
Suite 201
7106 Crossroads Blvd.
Brentwood, TN 37027
(615) 370-4242

Description and use: The Saf-T Clk consists of two components that lock together; one component has a short needle with a protective case that can fit a Luer adapter, and the other is a special injection adapter that fits into the first component.

List prices:

Cost/unit:

- \$0.98, Saf-T Clk
- \$0.43, protected needle adapter
- \$1.18 to \$1.30, connector with minibore tubing extension set
- \$0.56, heparin lock
- \$0.90, extension set with minibore J-loop tubing
- \$2.80, extension set with back-check valve
- \$1.90, extension set with slide clamp



Ryan Medical Saf-T Clk®
(as packaged [bottom], attached to a syringe as it might be used [top left], and the protected needle adapter)

Comments: This product is compatible with only the manufacturer's extension sets or special injection adapters attached to the catheter. The short needle component is protected with a cap that allows reuse if multiple injections are necessary. However, there may be a risk of infection if a new protected needle component is not used each time. The manufacturer is developing an additional extension set.

TRI-STATE HOSPITAL SUPPLY KLEEN-NEEDLE®
Tri-State Hospital Supply Corp. [103919]
301 Catrell Dr.
P.O. Box 170
Howell, MI 48843
(517) 546-5400; (800) 248-4058



Tri-State Hospital Supply Kleen-Needle®
(attached to a syringe as it might be used [top] and Kleen-Needle [bottom left] and heparin lock as packaged)

Description and use: The Kleen-Needle system consists of a short needle recessed in a plastic housing with a Luer lock on one end; the other end screws into Tri-State's own heparin lock (injection adapter). However, the needle part of the system can be used alone on a standard Y-site.

List prices:

Cost/unit:

- \$0.60, Kleen-Needle
- \$0.80, heparin lock

Comments: This product can be used for intermittent medications using existing IV sets or the manufacturer's heparin lock.



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Special Report and Product Review

Product Group 5: Blood Collection Systems

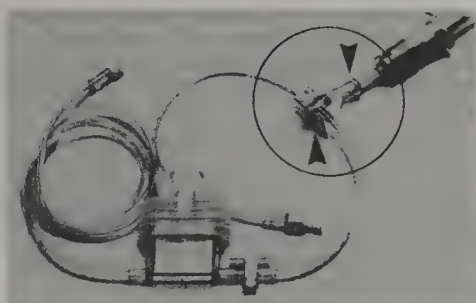
General description: This group is made up of two subgroups: blood collection tube adapters and an in-line collection system. Two of the devices are similar to conventional blood collection adapters that accept a needle and connect to the blood collection tube; the examined devices, however, have a protective sheath that can be positioned over the needle after use. The blood collection adapters are either reusable or disposable. (Standard blood collection devices are reusable; however, some hospitals may be disposing of them after each use.)

General effectiveness: Both disposable and reusable systems have their respective advantages and disadvantages. A disposable system should be effective after the needle is retracted; however, it costs more than a reusable system and is quite bulky, and carrying several blood adapters in a tray can be inconvenient for a phlebotomist (the manufacturer does provide a pouch for carrying adapters). Also, a large disposal container is needed to dispose of the adapter and needle. Although reusable systems provide a relatively safe way of recapping, the risk of needlestick is still present because the inner needle is exposed after unscrewing the needle from the adapter.

The Baxter/Edwards VAMP™ in-line system does not serve as a needlestick-prevention device, because a needle would not normally be used to draw blood from a transducer system; typically, a stopcock would be used for this purpose. However, this system does minimize blood leakage when drawing blood and may help minimize infection. Use of this device should also be monitored to determine any change in patient infection rate.

BAXTER/EDWARDS VAMP™
Baxter Healthcare Corp.
Edwards Critical-Care Div. [106431]
P.O. Box 11150
Santa Ana, CA 92711
(714) 250-2500; (800) 424-3278

Description and use: The VAMP (Venous/Arterial blood Management Protection) system is a closed, needleless system for drawing blood from a blood pressure transducer line. Blood can be drawn into a syringe or blood collection tube. A blunt cannula adapter is attached to a syringe, and the sample site is designed to accept the blunt cannula. The invasive line has a reservoir to contain the initial blood in the line; this blood is reinfused into the patient after the sample is withdrawn.



Baxter/Edwards VAMP™
(blunt cannula attached to a blood collection adapter [top arrow] and sample site [bottom arrow])

List prices:

Cost/unit:

\$19.00, VAMP kit

\$33.00, VAMP kit with transducer system

Comments: This system does not reduce the risk of needlesticks because the standard system would use a stopcock, which does not require a needle. The manufacturer claims that this system may reduce the risk of infection associated with Luer connectors at a stopcock.

MEDICAL SAFETY PRODUCTS ACCI-GUARD®
Medical Safety Products Inc. (MSPI) [108521]
Suite 500
2696 S. Colorado Blvd.
Denver, CO 80222
(303) 756-5151; (800) 677-1115



Medical Safety Products Acci-Guard®
(set up for use [left] and after use showing protected needle)

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Special Report and Product Review

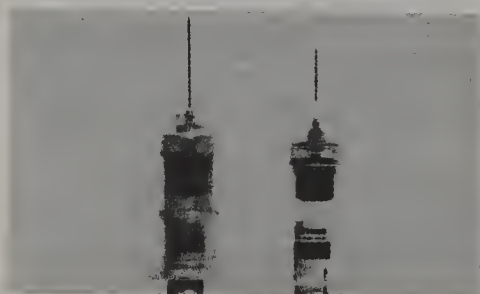
Description and use: The Acci-Guard is a reusable blood collection holder. After withdrawing blood, the needle is withdrawn into a plastic case, where it can safely be recapped. The needle must then be unscrewed and disposed of. It is compatible with sampling needles up to 1½" long.

List price:

Cost/unit: \$1.55 to \$1.95, Acci-Guard (estimated 200 uses)

Comments: This device helps reduce the risk of needlesticks. However, it may not be possible to use a screw-top disposal container. If the needle is manually unscrewed, the inner needle, which is covered only by soft rubber, presents the risk of needlestick.

RYAN MEDICAL BLOOD ADAPTER
Ryan Medical Inc. [108525]
Suite 201
7106 Crossroads Blvd.
Brentwood, TN 37027
(615) 370-4242



Ryan Medical Blood Adapter
(set up for use [left] and after use showing protected needle)

Description and use: The Blood Adapter has a sheath that locks over the outer needle after use. It is compatible with sampling needles up to 1½" long. The adapter is disposable and can be used only once.

List price:

Cost/unit: \$0.17, Blood Adapter

Comments: This device reduces the risk of needlesticks; however, the whole adapter must be discarded. This may be more costly and inconvenient to the user, who must carry an adapter for each patient (the manufacturer does provide a pouch for carrying adapters).



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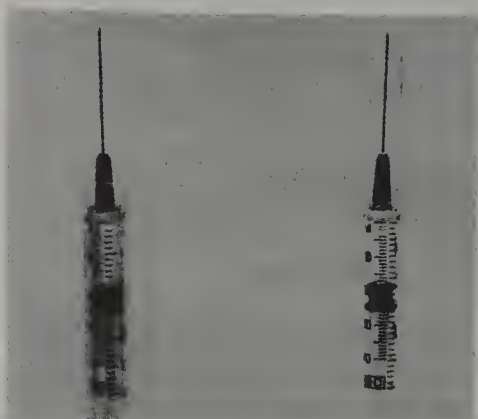
Product Group 6: Disposable Syringes

General description: The products in this group have a syringe and needle with a plastic sheath that locks over the needle after use. These devices can be used for IV or IM therapy and can reduce the risk of needlesticks. However, they are available in only limited sizes. Two manufacturers have only a 3 cc syringe. One manufacturer has safety syringes in different sizes, but only up to 5 cc. Other disadvantages include the additional disposal bulk and higher cost.

General effectiveness: These products are easy to use and offer excellent protection against needlesticks after the protective sheath is locked into position. However, available syringe sizes are extremely limited at present.

BECTON DICKINSON SAFETY-LOK™ SYRINGE
Becton Dickinson and Co.
Becton Dickinson Div. [101093]
One Stanley St.
Rutherford, NJ 07070
(201) 460-2000

Description and use: The Safety-Lok Syringe is a 3 cc syringe and needle combination used primarily to administer medication. It has a protective shield that the user locks in place over the needle after use and



Becton Dickinson Safety-Lok™ Syringe
(set up for use [left] and after use showing protected needle for disposal)

Special Report and Product Review

before disposal. This product is currently available in different needle sizes with only a 3 cc syringe.

List price:

Cost/unit: \$0.26, Safety-Lok

Comments: This product reduces the risk of needlesticks, but has limited applications.

NEEDLEPOINT GUARD SAFETY SYRINGE

NeedlePoint Guard Inc. [108060]
3969 Reuting Rd.
P.O. Box 1646
Grand Island, NE 68802-1646
(308) 384-3513; (800) 635-5878

Description and use: The Safety Syringe is a disposable syringe that has a protective shield that locks over the used needle. It is available in five different sizes — 0.5 cc, 1 cc (insulin and tuberculin), 3 cc, and 5 cc — with various needle gauges and lengths. The 5 cc syringe may be an adequate size for blood samples. The needle and the protective shield can be separated from the syringe to allow recapping of the syringe (e.g., for obtaining blood gas samples).

List prices:

Cost/unit:

\$0.36, 0.5 and 1 cc Safety Syringe
\$0.33, 3 and 5 cc Safety Syringe

Comments: This product reduces the risk of needlesticks and is the only product that is currently available in different sizes.

SHERWOOD MEDICAL MONOJECT®

Sherwood Medical Co.
Sub. American Home Products [101927]
1915 Olive St.
St. Louis, MO 63103
(314) 621-7788; (800) 325-7472

Description and use: The Monoject syringe has a protective sheath that extends over the needle and clicks into either of two positions. The first click position can be used to transport the medication to the patient's bedside without locking the sheath over the needle. The second click position is used to lock the sheath over the needle by turning the sheath in either direction. The Monoject is available with different gauge needles, but currently only in a 3 cc syringe.

List price:

Cost/unit: \$0.39, Monoject

Comments: This device reduces the risk of needlesticks. Protection against needlesticks during transport to the patient is an advantage, although the user may put the device at the first click position after the injection and assume it is permanently locked. Sherwood Medical also provides a safety feature in its



NeedlePoint Guard Safety Syringe
(set up for use [left] and after use showing protected
needle for disposal)

Sherwood Medical Monoject®
(set up for use [left] and after use showing protected
needle for disposal)

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Special Report and Product Review

standard syringes — a plastic holder for the needle cap that allows the user to perform one-handed recapping if properly trained, similar to a recapping device. This may be appropriate in some circumstances.



Product Group 7: Needle Guards

General description: This group includes needles with a guard that can be positioned over them after use. These can be purchased separately or with syringes. One manufacturer also provides the guard without a needle. Products in this group can be used with a syringe (including some prefilled syringes) or (for one manufacturer's product) to replace a blood collection needle.

General effectiveness: Needle guards provide one of the most adaptable designs for hospitalwide use of needlestick-prevention devices and reduce the risk of needlesticks after the protective sheath is locked into position. They also provide the hospital with one product that can be used to administer IV or IM medications, as well as to collect blood samples. However, the major limitations of this group include the cost increase over using a traditional needle and the possible awkwardness in using the device — the distance between the user's hand and the patient's vein is significantly greater because of the length of the needle guard; also, only limited needle gauges and lengths are currently available.

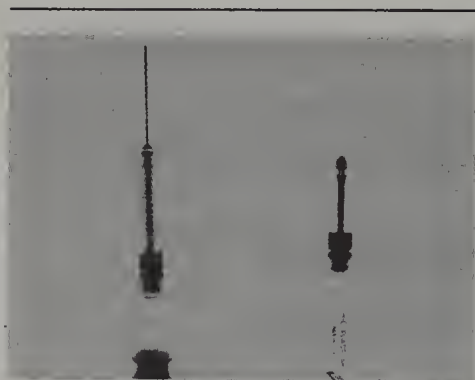
ICU MEDICAL HR NEEDLE™
ICU Medical Inc. [105658]
142 Technology Dr.
Irvine, CA 92718
(714) 753-1599; (800) 824-7890

Description and use: The HR Needle has a plastic sheath that covers the needle after use. It is available in different sizes and in a blood collection adapter version for drawing blood.

List price:

Cost/unit: \$0.40, HR Needle

Comments: This device can reduce the risk of needlesticks. It is available for use with syringes or blood collection systems. The user could get stuck with the inner needle of a blood collection needle when the user is disposing of it. However, some disposal containers allow the needle to be unscrewed directly into the container, avoiding this problem. Users may find the HR Needle



ICU Medical HR Needle™
(set up for use [left] and after use showing protected
needle for disposal)

awkward to use because the distance between the vein and the user's hand is doubled, which may make it difficult to control the needle during insertion.

NORTH AMERICAN MEDICAL PRODUCTS SAFE-SITE™
North American Medical Products (NAMP) Inc. [108522]
Bldg. 501
Rotterdam Industrial Park
East Rd.
Schenectady, NY 12306
(518) 356-8110

Description and use: The Safe-Site is a protective guard that extends over the needle and locks in place.



North American Medical Products Safe-Site™
(set up for use [left] and after use showing protected
needle for disposal)

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Special Report and Product Review

It is available with needle gauges 19, 20, 22, and 25 and needle lengths of $\frac{3}{4}$ ", $\frac{5}{8}$ ", and 1". It is also available separately for use with a user-supplied needle. The manufacturer will provide customized packages of other needle gauges and different syringe sizes. The guard can also be moved down to help stabilize it on a Y site for piggyback infusions.

List prices:

Cost/unit:

\$0.29, Safe-Site without needle and syringe

\$0.31, Safe-Site and needle

\$0.39, Safe-Site with needle and syringe

Comments: This device can reduce the risk of needlesticks. It can be used with a user-supplied needle of any gauge, but only up to 1" in length. However, this device doubles the distance between the user's hand and the patient's vein (or point of use), which may be awkward for some users.



Product Group 8: Needle-Recapping Devices

General description: This group includes any device that can be used to recap a needle to help prevent a needlestick.

General effectiveness: The two products examined have major limitations: (1) a recapping device is inconvenient because it will not always be readily available when it is needed, and users may avoid using it or forget to use it; and (2) it may not be compatible with some needle caps. An ideal needlestick-prevention device should be incorporated into the design of the needle so that it is readily available. A recapping device would need to be carried around by the user at all times and is not effective if the needle cap is misplaced or is not placed in the device initially. Because this device is separate from the needle, it is inconvenient, especially in emergency situations. In addition, the On-Gard Recapper™ is bulky, and needle caps sometimes fall into the device; the Terumo Safe-Guard shield appears too small to provide adequate protection.

However, there may be some applications for which a recapping device would be useful, and these devices are cost-effective. Some possible areas of use are the PACU, ICU/CCU, and dental clinics where medications are administered serially from a single syringe and must be recapped to maintain sterility. There may also be a need to recap during surgical procedures

and when obtaining blood gas samples (to prevent air contamination). Other methods of safe recapping, such as the one-handed scoop technique, require no additional devices, but do require a conveniently located flat surface.

ON-GARD SYSTEMS RECAPPER™

On-Gard Systems Inc. [108523]

Suite 710

1900 Grant St.

Denver, CO 80203

(303) 860-0723; (800) 878-8111



On-Gard Systems Recapper™

Description and use: The Recapper is used to recap needles after use. The cap is placed into the device before removing the needle. This device allows for the needle to then be safely recapped after use. Accessories available include a stand to allow one-handed recapping and a medical waste system that consists of two components: a sharps container and a container with disposable infectious waste bags.

List price:

Cost/unit: \$29.50, Recapper (reusable)

Comments: This product, like other recapping products, has major limitations as a needlestick-prevention device. It is bulky and inconvenient for the user to carry around, and during emergencies, the user may easily forget to use it. One hospital chained the device to each bed, but found that the health practitioners were still not using it. We also found that some of the caps fall into the device and are then difficult to remove. However, the recapper may have a role in controlled environments where recapping is necessary.

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Special Report and Product Review

Discussion and Recommendations

Selecting Needlestick-Prevention Devices for Four Clinical Applications

General Recommendations

Although a great number of needlestick-prevention products are available, none of the devices or systems that we examined are without limitations with regard to cost, applicability, and effectiveness. Some devices marketed as risk-reducing products offer no protection from needlesticks. The needlestick-prevention market will likely change as new designs are introduced and needs are better defined. The assessments included in this report should help users evaluate new products as they become available.

When purchasing any needlestick-prevention devices, users should consider a number of factors. The most important is whether the product will protect users from sticks with contaminated needles. If the device is used for applications in which needles are not normally used, or if it leaves the needle exposed after use, it will not reduce the risk of needlesticks.

Another factor is whether the product is compatible with existing products and whether additional products are needed. For example, some of the IV medication connectors have secure locking mechanisms, but if the hospital is not using the manufacturer's extension sets, these devices would then have to be used at the catheter site, which may not be convenient.

Assessing the extent of user training required for a product and whether the product could be easily misused is another important factor. Generally, using a product with a well-designed, convenient, integral protective mechanism will be more effective than relying heavily on training. Ideally, the device should require no user action (e.g., should have a recessed needle); otherwise, the action should be minimal and convenient. Users will be tempted to ignore or bypass any protective mechanism that is inconvenient or requires extra steps.

We strongly recommend that a hospital perform a clinical evaluation of each product of interest to determine its effectiveness and utility. The physicians, nurses, and other healthcare workers who will be using the systems are critical participants in clinical trials. Their input is often overlooked, even though they are the day-to-day users of the devices and are likely to make valuable contributions to the selection process, both in reviewing demonstration products and during

final decision making. Users who feel that a product is forced on them without their input are bound to find faults with the final selection and may fail to use it correctly. In addition, the Infection Control or Safety Committee should monitor these new devices for proper usage, for any increases in patient infection, and for any decrease in needlestick injuries, as well as the need for larger needle disposal containers or more frequent replacement of disposables (some prevention methods may add considerable bulk).

Because a single device will not meet all of a hospital's needs, users should carefully assess available products and attempt to select the minimum number of devices necessary. Using multiple devices increases the amount of training needed and the associated risk of confusion and misuse. The four main clinical applications we have identified in examining these devices are delivering IV medications, delivering IM/subcutaneous injections, introducing catheters, and collecting blood. In some cases, it may be possible to use the same product for more than one purpose (e.g., IV and IM injections).

Cost will also be a major concern. Hospitals should not pay an excessive amount to achieve only a minimal reduction in risk. In "Analyzing Costs Associated with Needlesticks and Preventive Devices," we discuss cost in greater detail and provide a sample CAHDM model.

Product Group Recommendations by Application

Based on our observations and our discussions with clinical consultants, we have provided guidance on the Product Groups that are most suitable for specific clinical uses. We caution readers not to base purchasing decisions on this abbreviated listing alone, but to review this entire Special Report and Product Review to gain perspectives on the efficacy of the examined products and the clinical issues surrounding their use.

Several of the products we examined are not recommended as needlestick-prevention devices. Products currently available in Product Group 2, prefilled medication systems, are similar to using a needle and syringe — the user is at risk from the exposed needle after it is used until it is disposed of. The in-line collection device in Product Group 5 does not normally

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Special Report and Product Review

Recommended Product Groups by Application

PRODUCT GROUP	APPLICATION				
	Delivering IV Medication Intermittent	Delivering IV Medication Secondary	Delivering IM/Subcu. Injections	Introducing Catheters	Collecting Blood
1. Needleless Medication/Vaccine Injectors	NA	NA	Yes	NA	NA
2. Prefilled Medication Systems	Not recommended as needlestick-prevention devices				
3. IV Starters with Catheters	NA	NA	NA	Yes	NA
4. IV Medication Connectors	Yes	Yes	NA	NA	NA
5. Blood Collection Systems	NA	NA	NA	NA	Yes*
6. Disposable Syringes	Yes	NA	Yes	NA	Yes
7. Needle Guards	Yes	Yes	Yes	NA	Yes
8. Needle-Recapping Devices	Have limited applications**				

* In-line connectors are not recommended as needlestick-prevention devices.

** See Product Group 8 in the Product Reviews.

require a needle to draw blood from a transducer system. And the needle-recapping products in Product Group 8 are not recommended for most applications, because they are not incorporated into the design of the needle device and may not always be readily available.

See the Recommended Product Groups by Application table for a list of the eight Product Groups and the clinical applications for which they are suitable and the Assessment of Manufacturers' Needlestick-Prevention Devices table for comments on individual products. Also, carefully review each Product Group before making a final purchasing decision. Below, we provide brief discussions on each application.

• Applications 1 and 2: Delivering IV Medications and Delivering IM (and Subcutaneous) Injections

We have combined these two applications because of the overlap in the available alternatives. IV applications can be broken into two subcategories — administering intermittent (push) medications and delivering secondary medications (piggybacking). Some devices may be suitable for both IV subcategories, as well as IM injections; other devices may be suitable for only one or two of these uses.

Also, some controversy exists among experts about the potential for cross-contamination when a needlestick injury occurs with a needle used for administering medications through the IV set. The risk of contact with the patient's blood appears to be less likely when administering drugs at a distance from the catheter site.

Product Group 1 — Needleless Medication/Vaccine Injectors

The single product that we examined in Group 1, the Bioject Biojector, has some limitations for IM applications and is not designed for IV applications. Currently, it can deliver only a 0.5 mL dose and may be less convenient on a nursing floor where several nurses may need the device at the same time. The Biojector is most useful where frequent vaccinations are being given, such as in a clinic.

Product Group 4 — IV Medication Connectors

Most of the products in this group meet the needs of both IV applications (intermittent and secondary), although each product should be assessed for these applications individually. The simplest devices are those that have a recessed needle and can be used on most catheter and IV-set Y-sites. However, use of these special protective connectors may require the user to remove or discard a needle already provided with existing supplies (e.g., a needle used to draw solution into a syringe from a medication container or packaged inside a secondary set). The other systems in this group are useful for only specialized applications or require converting the entire system (e.g., using special extension sets and other components). Complete conversion will probably be more complex and costly, but may be more effective for some hospitals than using a simpler system.

If the device manufacturer offers a secondary medication set with the preventive device, the possibility of using a needle that is typically supplied with secondary sets would be eliminated. Some users reportedly use tape at the Y-site to secure a secondary-set needle in place; this is not a recommended procedure. Although additional support should not be

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Special Report and Product Review

Assessment of Manufacturers' Needlestick-Prevention Devices

PRODUCT GROUP	MANUFACTURER	PRODUCT	PREVENTS NEEDLESTICK	COMMENTS
1. Needleless Medication/ Vaccine Injectors	BIJECT	Biojector [®]	Yes	Limited IM applications; delivers only a 0.5 mL dose
2. Prefilled Medication Systems	WINTHROP PHARMACEUTICALS	Carpuject [®]	No	Requires sharps container; may help minimize medication errors
	WYETH-AYERST	Tubex [®]	No	Requires sharps container; may help minimize medication errors
3. IV Starters with Catheters	CRITIKON	ProtectiV™	Yes	Poses hazard if misplaced in linens or if splashed in eye
	DESERET MEDICAL	Intima™	Limited	
	MENLO CARE	Landmark [®]	Yes	Intended for intermediate-term use; limited applications
	RYAN MEDICAL	Shamrock™	Yes	Uses a steel needle intended for short-term use
4. IV Medication Connectors	BAXTER HEALTHCARE	Interlink™ IV Access System	Yes	Need to use manufacturer's injection adapters
	BAXTER HEALTHCARE	Needle™Lock™	Yes	Useful for piggyback medications
	BURRON MEDICAL	Safsite™	Yes	Need to use manufacturer's injection adapters*
	ICU MEDICAL	Click Lock™	Yes	Not compatible with some IV sets and catheters*
	IMS	Stick-Gard™	Yes	May be less expensive
	L & W TECHNOLOGY	Safeport™	Yes	Limited applications
	PASCALL MEDICAL	SPIVE	Yes	Limited applications
	RYAN MEDICAL	Saf-T Click [®]	Yes	Need to use manufacturer's injection adapters
5. Blood Collection Systems	TRI-STATE HOSPITAL SUPPLY	Kleen-Needle [®]	Yes	Compatible with existing equipment
	BAXTER/EDWARDS	VAMP™	No	For use only with blood pressure lines
	MEDICAL SAFETY PRODUCTS	Acci-Guard [®]	Yes	May pose risk of inner-needle exposure
	RYAN MEDICAL	Blood Adapter	Yes	Effective, but may be inconvenient to user
6. Disposable Syringes	BECTON DICKINSON	Safety-Lok™ Syringe	Yes	Available in only 3 cc syringes
	NEEDLEPOINT GUARD	Safety Syringe	Yes	Available up to 5 cc size
	SHERWOOD MEDICAL	Monoject [®]	Yes	Available in only 3 cc size; has 2-position lock
7. Needle Guards	ICU MEDICAL	HR Needle™	Yes	Used with syringes and blood adapters; for hospitalwide use, but is awkward
	NORTH AMERICAN MEDICAL	Safe-Site™	Yes	Available alone or with needles/syringes; for hospitalwide use, but is awkward
8. Needle-Recapping Devices	ON-GARD SYSTEMS	Recapper™	See text	Not recommended for most locations; may not be available when needed
	TERUMO	Safe-Guard Shield	See text	Not recommended for most locations; may not be available when needed

* Manufacturer plans to introduce a new product that will be compatible with other manufacturers' components.

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Special Report and Product Review

required, some of the examined devices may provide more support or lock in place.

Product Group 6 — Disposable Syringes

These syringes can be used for intermittent IV and IM injections, but not for secondary sets. At present, their overriding disadvantage is that they come in an inadequate range of sizes.

Product Group 7 — Needle Guards

These devices are versatile enough to be used not only for intermittent and secondary IV applications, but also for IM applications. However, the extra length of the guard may make it awkward when using secondary sets and during IM injections. Hospital clinicians should investigate this before making a purchasing decision.

• Application 3: Introducing Catheters

Product Group 3 — IV Starters with Catheters

The four products that we examined represent different clinical applications and have different needlestick-prevention designs. Three of these products appear to effectively reduce the risk of needlesticks. The Critikon ProtectIV can be used to replace many common catheters. The Menlo Care Landmark catheter is expensive and is primarily intended for intermediate-term and special applications. The Ryan Medical Shamrock is appropriate only for short-term use and where its metal needle will not be a problem; it provides protection as long as the user remembers to properly cover the needle. The Deseret Intima reduces some of the risk of needlesticks,

but can still pose a significant hazard — for example, if misplaced in linens. Thus, hospitals will need to consider specific clinical needs and determine whether these or other products are appropriate.

• Application 4: Collecting Blood

Product Group 5 — Blood Collection Systems

Both disposable and reusable systems have advantages and disadvantages. Although reusable systems do not eliminate the risk of needlesticks because the inner needle is exposed after unscrewing the needle from the adapter, they do provide a relatively safe way of recapping. The disposable adapters eliminate the need to recap (and also the exposure to the needle). However, disposable adapters are bulkier, making them more difficult to carry and creating greater disposal bulk, and they are more costly than reusables.

As mentioned above, in-line collection products are not needlestick-prevention devices.

Product Group 6 — Disposable Syringes

Refer to the comments for Applications 1 and 2. Also, because of the syringe sizes, the amount of blood that can be collected would be limited.

Product Group 7 — Needle Guards

Refer to the comments for Applications 1 and 2. Also, needle guards would be disposed of in a manner similar to reusable adapters (i.e., the inner needle would be exposed). Users should determine whether they would be awkward to use before purchasing these devices.

Analyzing Costs Associated with Needlesticks and Preventive Devices

Needlestick-prevention devices usually cost more than comparable nonpreventive devices currently being used in most hospitals. This cost increase, however, may be offset by savings that result from a decreased number of needlesticks. Because questions will likely be raised by studies published in the literature or presented by manufacturers (e.g., what factors must be considered in assessing cost?), below we discuss some of the costs associated with needlestick injuries and present the results of one published report, in which the authors compared the costs of using nonpreventive and preventive devices.

Rather than attempting to duplicate this study, and because needlestick-prevention devices are necessary for personnel safety, hospitals should concentrate on conducting a cost comparison among preventive alternatives to determine the most cost-effective systems for their institution. The second

half of this article provides guidance on how to perform such a comparison.

The Cost of a Needlestick

The cost of occupational needlestick injuries will depend on the needlestick follow-up procedures taken; the procedures necessary will vary depending on the likelihood of infection. When the source of the needle is known and HIV or HBV contamination is unlikely, prophylactic treatment may be limited to testing the patient (source) for HIV and HBV, testing the person receiving the needlestick for adequate HBV and possibly HIV antibodies, and administering gamma globulin. When the source is unknown or is likely to have been HIV or HBV infected, additional measures may be appropriate, possibly including prophylactic zidovudine (Retrovir®) treatments, which may help to

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Special Report and Product Review

reduce the risk of AIDS. (The use of zidovudine in this context is still controversial.)

Assessing needlestick injury costs requires determining the number of needlesticks occurring in the hospital, classifying these incidents according to the extent (and cost) of treatment, and then calculating total postneedlestick prophylactic treatment. In addition, cost estimates associated with lost time, Worker's Compensation insurance, and possible legal costs and liability in the event of a lawsuit should be considered. Some of this data may be impossible to estimate accurately, especially liability costs; one successful liability claim could easily override all other considerations.

Cost estimates published in the literature or provided by manufacturers should be carefully examined. Determine whether these estimates are based on actual costs to the hospital or typical patient charges for those laboratory procedures. Personnel time costs (e.g., for the infection control nurse) should be included only if the amount of time is significant enough to justify staffing changes.

In a recent study (Jagger, Hunt, and Pearson 1990), the average cost for a needlestick (treatment, prophylaxis, and employee health department personnel time) was \$405, with the largest portion of the total cost (60%) being hepatitis screens. Using the costs of six conventional needled devices currently in use, the authors calculated the cost of a needlestick as a percentage of the cost of the device that caused the injury. Because of the often large price differences between different devices, the percentages varied widely. For example, needlesticks caused by IV catheters (stylets) cost only 10% of the device's purchase price, whereas needlesticks caused by IV tubing needle assemblies cost 457%. (The other percentages were 23% for disposable syringes, 27% for butterfly needle IV sets, 57% for prefilled cartridge syringes, and 157% for vacuum tube phlebotomy sets.) On average, needlesticks cost an overall 36% above the purchase price of the devices. Thus, a hospital could pay an additional 36% for preventive devices (assuming that they would totally eliminate the costs associated with needlesticks) without increasing total costs.

Cost Comparisons of Preventive Alternatives

Regardless of the cost of needlestick follow-up, hospitals are obligated to provide adequate preventive measures for their employees. Industry and government standards are likely to reinforce this obligation, as discussed in the introduction to this report. Therefore, a primary concern for hospitals is selecting the most cost-effective preventive strategy. Needlestick-prevention devices will likely be a critical component

in such a program; however, these products vary considerably not only in cost, but also in effectiveness, as discussed in this report.

The following discussion provides guidance on making a cost comparison among products under consideration for preventing needlesticks (effectiveness must be addressed using the guidance in the Product Review section and "Selecting Needlestick-Prevention Devices for Four Clinical Applications" earlier in this section). We also reemphasize the need for clinical trials. While we present some illustrative examples here, these should not be interpreted as necessarily typical or appropriate for an individual hospital. To enable each hospital to examine its own specific cost issues, we have provided a CAHModel for one needlestick application that incorporates the principles below. Specific instructions for using the CAHModel and entering institutional data are provided in the CAHModel software. (Also, see pages 149 to 153 for a general description of CAHD.)

Because most hospitals are concerned with the impact of needlestick-prevention devices on their budget, we suggest comparing the cost of using each new alternative to the cost of using current conventional (nonpreventive) devices, then using this difference for comparing alternative preventive products. This method will show how each new alternative under consideration compares with current costs and will also help organize institutional thinking in considering all the changes that will be required in converting from the current system to an alternative system.

Three major guidelines should be used in this cost assessment. First, calculate prices on an annual basis; using costs per use, cost per patient, or other similar comparisons can be misleading. Because the marketplace is likely to change rapidly, estimates should be made for no more than a one-year period. Prices used should be those negotiated with the supplier; list prices can also be misleading.

Second, in performing a comparison, include all relevant costs in the analysis of each alternative. For example, if you will be switching the type of syringe used, include the cost of the old syringes in the cost of the current system and the cost of the new syringes in the alternative system. Do not include costs that are common to both alternatives (e.g., in the previous example, if the same syringe is used in both alternatives, exclude it from the calculation because it will have no impact on the cost difference).

Third, the analysis should take into account all clinical applications. These will usually fall into the four categories identified in "Selecting Needlestick-

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Special Report and Product Review

CAHDMODEL

APPLICATION: DELIVERING IV MEDICATIONS

Alternative 1				Alternative 2			
Preventive Devices	Units/Yr	\$/Unit	\$/Yr	Preventive Devices	Units/Yr	\$/Unit	\$/Yr
Disposable syringes/needles, 1 cc	20,000	\$0.35	\$7,000	Needle guards/needles for secondary med sets	20,000	\$0.40	\$8,000
Disposable syringes/needles, 3 cc	50,000	\$0.35	\$17,500	Needle guards/needles-syringes	110,000	\$0.40	\$44,000
Disposable syringes/needles, 5 cc	30,000	\$0.33	\$9,900	Conventional syringes, 1 cc	20,000	\$0.20	\$4,000
Recessed needle for 10 cc syringes	10,000	\$0.20	\$2,000	Conventional syringes, 3 cc	50,000	\$0.20	\$10,000
Conventional syringes, 10 cc	10,000	\$0.18	\$1,800	Conventional syringes, 5 cc	30,000	\$0.20	\$6,000
Secondary med sets/recessed needles	20,000	\$3.50	\$70,000	Conventional syringes, 10 cc	10,000	\$0.18	\$1,800
TOTAL ANNUAL COST			\$108,200	TOTAL ANNUAL COST			\$73,800
Currently Used Devices				Currently Used Devices			
Disposable syringes/needles, 1 cc	20,000	\$0.22	\$4,400	Disposable syringes/needles, 1 cc	20,000	\$0.22	\$4,400
Disposable syringes/needles, 3 cc	50,000	\$0.22	\$11,000	Disposable syringes/needles, 3 cc	50,000	\$0.22	\$11,000
Disposable syringes/needles, 5 cc	30,000	\$0.20	\$6,000	Disposable syringes/needles, 5 cc	30,000	\$0.20	\$6,000
Disposable syringes/needles, 10 cc	10,000	\$0.20	\$2,000	Disposable syringes/needles, 10 cc	10,000	\$0.20	\$2,000
Secondary med sets/needles	20,000	\$2.00	\$40,000	TOTAL ANNUAL COST			\$23,400
TOTAL ANNUAL COST			\$63,400				
TOTAL ANNUAL COST DIFFERENCE			\$44,800	TOTAL ANNUAL COST DIFFERENCE			\$50,400

Prevention Devices for Four Clinical Applications": delivering IV medications, delivering IM (and subcutaneous) injections, introducing catheters, and collecting blood. The Recommended Product Groups by Application table on page 175 shows the Product Groups discussed in our Product Reviews that might be appropriate for each application. Because of the overlap between applications and device types, the analysis should encompass all anticipated changes. For example, needle guards can be used for both IV and IM applications. An overall assessment allows alternatives to be compared and cost differences to be kept in perspective.

The sample CAHDMODEL output above illustrates a cost analysis of products used for delivering IV medications. This model compares the costs of two proposed alternative systems using preventive devices with current systems using nonpreventive devices. Note the cost differences between Alternatives 1 and 2. (This sample is intended for illustrative purposes only; actual output may vary.)



Cost analysis following these principles will provide a useful guide in estimating the cost of preventive devices, compared both with current devices and with other similar devices. The CAHDMODEL will guide your analysis and perform the necessary calculations for you. Although cost is certainly important, product effectiveness, training requirements, and user accep-

tance are also key issues that must be considered before making a decision, as discussed in this report.

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P. 02

Table 3. AIDS cases by age group, exposure category, and sex, reported in 1990 and 1991; and cumulative totals, by age group and exposure category, through December 1991, United States

Adult/adolescent exposure category	Males		Females		Totals		Cumulative total ¹
	1990 No. (%)	1991 No. (%)	1990 No. (%)	1991 No. (%)	1990 No. (%)	1991 No. (%)	
Men who have sex with men	24,053 (64)	23,960 (61)	—	—	24,053 (57)	23,960 (53)	118,362 (58)
Injecting drug use	7,769 (21)	6,403 (21)	2,392 (49)	2,752 (48)	10,161 (24)	11,155 (25)	45,753 (23)
Men who have sex with men and inject drugs	2,445 (6)	2,366 (6)	—	—	2,445 (6)	2,366 (5)	13,135 (6)
Hemophilia/coagulation disorder	329 (1)	314 (1)	9 (0)	10 (0)	338 (1)	324 (1)	1,713 (1)
Homosexual contact:	1,081 (3)	1,292 (3)	1,718 (35)	2,095 (37)	2,799 (7)	3,387 (8)	11,936 (6)
Sex with injecting drug user	495	559	1,105	1,239	1,600	1,798	6,366
Sex with bisexual male	—	—	135	147	135	147	651
Sex with person with hemophilia	2	4	26	21	28	25	104
Born in Pattern-II ² country	303	335	110	174	413	510	2,523
Sex with person born in Pattern-II country	24	20	22	24	46	44	174
Sex with transfusion recipient with HIV infection	26	27	43	56	69	83	240
Sex with HIV-infected person, risk not specified	231	346	277	434	508	780	1,678
Receipt of blood transfusion, blood components, or tissue ³	492 (1)	456 (1)	354 (7)	250 (4)	846 (2)	706 (2)	4,347 (2)
Other/undetermined ⁴	1,507 (4)	2,302 (6)	415 (8)	623 (11)	1,922 (5)	2,925 (7)	7,675 (4)
Adult/adolescent subtotal	37,676 (100)	39,093 (100)	4,888 (100)	5,730 (100)	42,564 (100)	44,823 (100)	202,621 (100)
Pediatric (<13 years old) exposure category							
Hemophilia/coagulation disorder	31 (7)	22 (6)	—	1 (0)	31 (4)	23 (3)	163 (5)
Mother with at risk for HIV infection:	346 (83)	318 (86)	347 (94)	276 (88)	693 (88)	598 (87)	2,936 (85)
Injecting drug use	170	136	151	122	321	258	1,430
Sex with injecting drug user	74	56	79	52	153	108	603
Sex with bisexual male	5	5	6	6	11	11	61
Sex with person with hemophilia	1	4	1	—	2	4	13
Born in Pattern-II country	22	23	20	9	42	32	244
Sex with person born in Pattern-II country	2	1	4	—	6	1	14
Sex with transfusion recipient with HIV infection	1	—	—	1	1	1	13
Sex with HIV-infected person, risk not specified	15	28	23	14	38	42	144
Receipt of blood transfusion, blood components, or tissue	5	8	7	7	12	15	60
Has HIV infection, risk not specified	51	57	56	67	107	124	354
Receipt of blood transfusion, blood components, or tissue	27 (6)	21 (6)	11 (3)	20 (6)	38 (5)	41 (6)	289 (8)
Undetermined	14 (3)	7 (2)	12 (3)	16 (5)	26 (3)	23 (3)	83 (2)
Pediatric subtotal	418 (100)	368 (100)	370 (100)	315 (100)	788 (100)	683 (100)	3,471 (100)
Total	38,094	39,461	5,258	6,045	43,352	45,506	206,392

¹Includes 3 patients known to be infected with human immunodeficiency virus type 2 (HIV-2). See MMWR 1989;36:572-580.

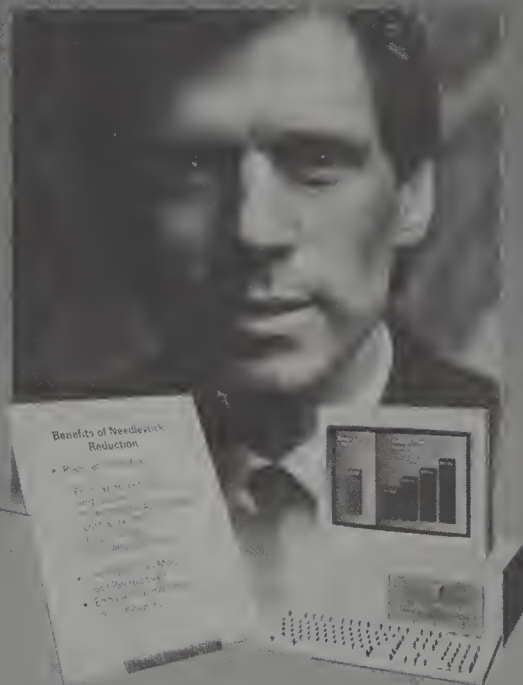
²See technical notes.

³Eighteen adults/adolescents and 2 children developed AIDS after receiving blood screened negative for HIV antibody. Five additional adults developed AIDS after receiving tissue or organs from HIV-infected donors. Two of the five received organs or tissue from a donor who was negative for HIV antibody at the time of donation.

⁴"Other" refers to 4 persons who developed AIDS after exposure to HIV-infected blood within the health care setting, as documented by evidence of seroconversion or other laboratory studies. "Undetermined" refers to patients whose mode of exposure to HIV is unknown. This includes patients under investigation; patients who died, were lost to follow-up, or refused interview, and patients whose mode of exposure to HIV remains undetermined after investigation. See Figure 6.

What's New **BD**

An Analysis Demonstrating Needlestick Cost Reductions



Safety
Compliance
Productivity
Cost Savings
Environmental

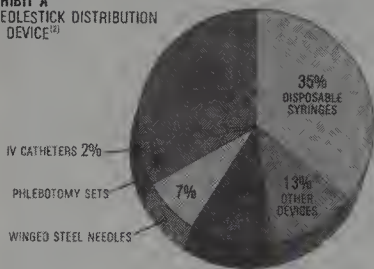
The B-D Sharps Safety System will reduce your total needlestick injury costs.

The two largest components of a hospital's total hypodermic expenditures are product acquisition costs and the treatment costs associated with managing accidental needlesticks. Based upon reported U.S. needlestick rates and treatment protocols, it is common for a hospital's direct needlestick treatment costs to be more than double its product acquisition costs.

Becton Dickinson shares your commitment

As illustrated in Exhibit A, almost 75% of needlesticks involve accidents with hypodermic products (syringes, needles on I.V. tubing assemblies, and prefilled cartridge syringes). Becton Dickinson is committed to helping you substantially reduce these risks through use of the comprehensive B-D Sharps Safety System.

EXHIBIT A
NEEDLESTICK DISTRIBUTION
BY DEVICE⁽¹⁾



In addition to this financial impact, there is a significant "human cost" as well. Accidental needlesticks literally change the lives and lifestyles of the victims, and can result in potentially fatal consequences. Controlling the financial and human costs of accidental needlesticks is among the greatest challenges confronting hospitals today.

A customized safety analysis for your hospital.

Exhibit B reveals potential needlestick reductions and related cost savings available with the B-D Sharps Safety System. Exhibit C provides a detailed example for a typical 300 bed hospital.

EXHIBIT B
NEEDLESTICK REDUCTION POTENTIAL
(EDUCATION, PRODUCT & DISPOSAL SOLUTIONS)



EXHIBIT C
ANNUAL HYPODERMIC ACQUISITION/NEEDLESTICK MANAGEMENT COSTS
(EXAMPLE - 300 BED HOSPITAL)

1. Acquisition Costs¹		Dollar Purchase Volume
Syringes		\$54,100
Needles		+ 6,300
Prefilled Cartridge Syringes		+ 12,789
TOTAL ACQUISITION COSTS		\$ 73,189
2. Post Exposure Management Costs²		
Annual Needlesticks	249	
Treatment Costs Per Stick ³	x \$ 600	
TOTAL TREATMENT COSTS		\$149,400
TOTAL COMBINED COSTS		\$222,589

3. NEEDLESTICK COST REDUCTION OPPORTUNITIES

DEVICE CATEGORY ⁴	Number of Sticks	Cost per Stick Dollars	POTENTIAL COST SAVINGS					
			Education/Awareness ⁵		Product Solutions ⁶		Disposal Solutions ⁴	
			Percent	Dollars ⁷	Percent	Dollars ⁸	Percent	Dollars
Syringes	87	600	10	5,220	80	41,760	-	-
I.V. Tubing Assemblies	66	600	10	3,960	80	31,680	-	-
Cartridge Syringes	30	600	10	1,800	80	14,400	-	-
Winged Steel Needles	18	600	10	1,080	-	-	15	1,620
Phlebotomy Sets	12	600	10	720	-	-	15	1,080
I.V. Catheters	3	600	10	180	-	-	15	270
Other	33	600	10	1,980	-	-	15	2,970
TOTAL	249	\$600	10%	\$14,940	59%	\$87,840	4%	\$5,940

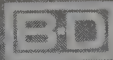
4. Combined Savings: Education, Product & Disposal Solutions⁵ **73 PERCENT** **104,720 DOLLARS**

FOOTNOTES:

1. Acquisition costs are based upon an average annual consumption rate of 1900 syringes per bed, 600 needles per bed and 95 prefilled cartridge syringes per bed.
2. Post exposure management costs are derived using a needlestick rate of 0.83 sticks per bed and an average treatment cost of \$600 per stick.⁽¹⁾
3. This estimated treatment cost per needlestick covers only direct expenses. Not included in this number are indirect expenses associated with insurance rates, legal liabilities, OSHA fines, staff recruiting and public relations.
4. This example is based upon a distribution of needlesticks among the seven categories as follows: Syringes 35%, I.V. Tubing Assemblies 26%, Prefilled Cartridge Syringes 12%, Winged Steel Needles 7%, Phlebotomy Sets 5%, I.V. Catheters 2%, Others 13%.⁽²⁾
5. Estimates of savings in all Device Categories attributed to Education/Awareness result from anecdotal data supplied by hospitals that implemented Becton Dickinson's Safety Compliance Initiative™ program (SCI) as part of their in-house risk reduction education programs.
6. Savings illustrated are exclusive of the costs of purchasing alternate educational programs (estimated at \$800-\$4,500). SCI may be available at no charge to qualifying hospitals.
7. Estimates of savings from Product Solutions are derived as follows:
 - Safety-Lok™ Syringes will eliminate 42% of needlesticks involving syringes.
 - InterLink™/Safety-Gard™ will eliminate 38% of needlesticks involving syringes and 80% of needlesticks involving I.V. tubing connections.
8. Savings calculated for product solutions are exclusive of any additional costs associated with purchases of Safety-Lok™ Syringes, the InterLink™ I.V. Access System and Safety-Gard™ I.V. Needles.
9. Estimates of savings from Disposal Solutions are based upon adoption of the new **620** Guardian Sharps Collectors with side and/or horizontal entry.⁽⁶⁾
10. All percentages used in the cost reduction calculations represent the mid-point of a range that is $\pm 5\%$. For example, the 10% reduction attributed to education reflects the mid-point of a range between 5% and 15%. Likewise, the resultant dollar savings are the mid-point of a similar range.

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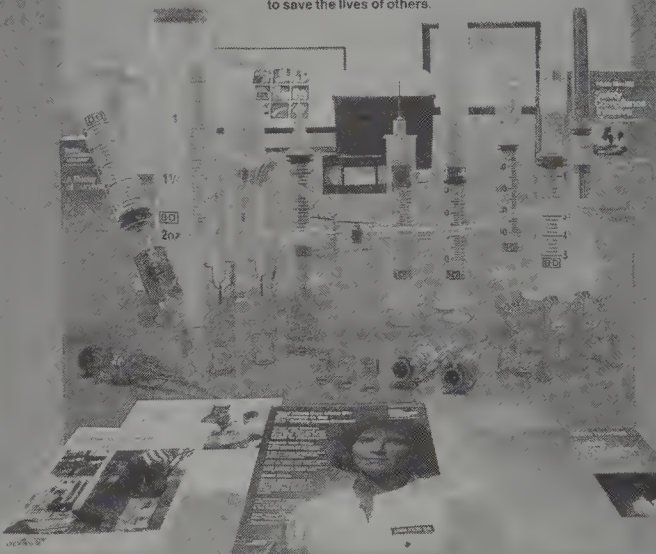
A Comprehensive System for Sharps Safety

Becton Dickinson, the world's leading manufacturer of sharps products, is totally dedicated to significantly reducing the risk of sharps injuries worldwide. As part of this commitment, we offer the only comprehensive system for sharps safety:

- Programs for awareness, education, motivation.
- Safer products to reduce or eliminate risk in use.
- Safer collectors to reduce risk during containment.
- Services for safer sharps waste disposal.

This system is designed to complement the most vital component of risk reduction — your own commitment to extend the highest degree of safety to the compliance procedures and sharps products utilized within your facility.

Together, we can help ensure healthcare workers do not have to unnecessarily risk their own lives to save the lives of others.



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Sharps Safety System Analysis Worksheet

Account Name _____		Bed Size _____	Nº 0074
City _____	State _____	Territory Number _____	
Individual _____		<input checked="" type="checkbox"/> Representative _____	
Title _____			

ANNUAL HYPODERMIC ACQUISITION/NEEDLESTICK MANAGEMENT COSTS

1. Acquisition Costs	Dollar Purchase Volume
Syringes	_____
Needles (non-I.V. set connections)	_____
Needles (I.V. set connections)	_____
Prefilled Cartridge Syringes	_____
TOTAL ACQUISITION COSTS	_____
2. Post Exposure Management Costs	
Annual Needlesticks	_____
Treatment Costs Per Stick	\$ _____
TOTAL TREATMENT COSTS	_____
TOTAL COMBINED COSTS	_____

3. NEEDLESTICK COST REDUCTION OPPORTUNITIES

DEVICE CATEGORY	Number of Sticks	Cost per Stick Dollars	POTENTIAL COST SAVINGS					
			Education/Awareness		Product Solutions		Disposal Solutions	
			Percent	Dollars	Percent	Dollars	Percent	Dollars
Syringes			10		80			
I.V. Tubing Assemblies			10		80			
Cartridge Syringes			10		80			
Winged Steel Needles			10				15	
Phlebotomy Sets			10				15	
I.V. Catheters			10				15	
Other			10				15	
TOTAL			10%					

4. Combined Savings: Education, Product & Disposal Solutions⁹ _____ PERCENT _____ DOLLARS

Directions for completing the Sharps Safety System Cost Analysis Worksheet

- In Section 1, enter hospital dollar volume for purchases of syringes, needles and prefills and total to calculate acquisition costs. If data is not available, use: Syringes - \$180 per bed, Needles - \$21 per bed, Prefills - \$43 per bed.
- In Section 2, enter annual needlesticks and treatment cost per needlestick. Multiply sticks x costs to calculate total treatment costs. If data is not available, use: 0.83 needlesticks per bed times bed size to calculate number of sticks. Treatment costs range from \$400 to \$1,000 per stick.
- Add Acquisition Costs and Treatment Costs to calculate Total Combined Costs.
- In Section 3, enter the number of needlesticks in each Device Category. If data is not available, multiply the total needlesticks in Step 2 above by the percentage for each category listed in Footnote 4 or Illustration A.
- Enter the Cost per Stick in each category. If data is not available, enter the cost used in Step 2 above in each category.
- Calculate the Potential Dollar Savings for Education/Awareness as follows: Multiply the Number of Sticks in the Device Category times the Cost per Stick times the Percent Reduction and enter the result in the shaded square.
Repeat for each category of needlestick and total the dollar savings to the bottom of the column.
- Repeat Step 6 for Product Solutions and Disposal Solutions.
- Calculate the Combined Savings in Section 4 by adding the savings calculated for Education/Awareness, Product Solutions and Disposal Solutions. Divide this amount by the Total Treatment Costs in No. 2 to calculate the percent savings.

White: Customer

Canary: Marketing

Pink: Regional Sales Office

Gold: Sales Representative



SHARP-TRAP® INC.

15777 West Ten Mile
Suite 200
Southfield, Michigan 48075
U.S.A.

1-313-552-1190
Fax 1-313-552-0332

Chairman Ron Wyden
Small Business Subcommittee
on Regulations, Business Opportunities and Energy
B363 Rayburn
Washington D.C. 20515

February 3, 1992

Dear Chairman Wyden,

I am writing to introduce you to a concept and device that I developed which I feel is closely related to the focus of the upcoming Subcommittee hearing you will be chairing February 7, 1992. I am confident that my device provides a viable solution to a very serious problem facing the medical community today -- medical sharps containment, transport and disposal.

The device of which I speak is called the SHARP-TRAP. SHARP-TRAP is patented in the United States and abroad and was reviewed successfully by the F.D.A. in May of 1990. SHARP-TRAP is a small puncture-proof container with a trap door mechanism for entry. The entry system is designed to allow very quick and easy sharps deposit, yet in such a way as to prevent any sharps from escaping. This design provides for both simplicity and safety in a portable and versatile form.

The repercussions of improper handling of contaminated medical sharps are far reaching and multifaceted. Perhaps the scariest of these is the threat of contracting AIDS through percutaneous exposure. This not only threatens the medical professional performing the procedure, it also threatens anyone who handles those instruments post procedure. Along with the obvious health risks, there are financial implications which should be examined. The average cost incurred for blood tests after a needle prick is \$678.00. This translates into an estimated cost of over 524 million dollars of avoidable insurance expenditures each year. In light of the current national scrutiny of rising health costs this becomes a very important issue. In addition, needle care at home must be examined as it pertains to the diabetic population. There are currently no standardized guidelines for the disposal of insulin syringes. This creates a potential needle prick hazard for everyone, from the local Department of Public Waste worker, to the curious neighborhood child, to the recycling facility employee who is faced with the task of removing these used syringes from the pop bottles or milk jugs they have been deposited in.

SHARP-TRAP® INC.

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U.S.A.

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The concept I envision is really quite simple. I suggest medical sharps be deposited, by the user, directly in an escape-proof device immediately after use. This practice could virtually eliminate secondary handling of contaminated sharps and would serve to greatly reduce the occurrence of millions of puncture wounds being sustained by medical professionals in the U.S.A. every year. In addition to the need for a solution among medical professionals, we also have millions of diabetics who lack a safe method for needle disposal. The SHARP-TRAP can fill this void. While providing safety and convenience to the users of medical sharps, this device would also protect those with responsibility of transporting these contaminated instruments to landfills, incinerators and recycling facilities.

The SHARP-TRAP is already enjoying tremendous popularity among the medical professionals who have been exposed to it. N.A.S.A. has used it at zero-gravity for disposal of CVP and subclavian insertion instruments and they are considering including it in their medical kits.

I would like to see major liability insurance carriers encourage the use of sharps containment systems by reducing premiums for conscientious users. I would also like to see major medical insurance carriers encourage use by diabetics by covering the device as a prescription item. Furthermore, in light of the seemingly uncontrollable proliferation of AIDS, I would like to see comprehensive government regulations regarding the handling and disposal of contaminated medical sharps.

Please take my thoughts and recommendation into consideration when exploring these issues of February 7. Thank you.

Respectfully,

Rick Sawaya M.D.
Rick Sawaya, M.D.

SHARP-TRAP® INC.

15777 West Ten Mile
Suite 200
Southfield, Michigan 48075
U.S.A.

1-313-552-1190
Fax 1-313-552-0332

Grady Forer
C/O Subcommittee on Regulations
B363 Rayburn
Washington DC 20515

Mr. Forer,

I am writing to introduce you to a concept and a device that I developed which I feel is closely related to the focus of the upcoming Subcommittee hearing you will be attending February 7, 1992. I am confident that my device provides a viable solution to a very serious problem facing the medical community today — medical sharps containment, transport and disposal.

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The concept I envision is really quite simple. I suggest that the sharp medical instruments be deposited, by the user, directly in an escape-proof device ^{immediately} after use. This practice could eliminate secondary handling of contaminated sharps. This would serve to greatly reduce the occurrence of millions of puncture wounds being sustained by medical professionals in the U.S.A. every year. In addition to the need for a solution among medical professionals, we also have millions of diabetics who lack a standardized method for needle disposal. The SHARP-TRAP can fill this void. While providing safety and convenience to the users of medical sharps, this device would also protect those with the responsibility of transporting these contaminated instruments to landfills and incinerators.

The SHARP-TRAP is already enjoying tremendous popularity among the medical professionals who have been exposed to it. N.A.S.A. has used it at zero-gravity for disposal of CVP and subclavian insertion instruments and they are considering including it in their medical kits.

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Please take my thoughts and recommendations into consideration when you attend the hearing on February 7. Thank you.

Respectfully,

Rick Sawaya MD

*** The CDC recently told me that there were too many needles and syringes in pop cans to recycle them properly.* Jan 29, 1992.
The complaint came from a recyclin factory.

SHARP-TRAP® INC.

15777 West Ten Mile
Suite 200
Southfield, Michigan 48075
USA.

1-313-552-1190
Fax 1-313-552-0332

Oct. 4. 1991.

Enclosed is a description of the only self-closing sterile and non-sterile sharp's container in the world. With its self-closing, overlapping doors, the box has successfully passed space-flights in zero-gravity testing cvp lines, arterial punctures, mouse surgery, needle counters etc.

It is a handy ashtray system which eliminates the need for transporting the needles, and puts the responsibility in the hands of the skilled physician

It is transparent, light-weight and capable of holding entire instrument trays, CVP's, Minor Suture Sets etc.

The Sharp-Trap is currently used by major hospitals, being tested by McKesson Drugs for use by the diabetics for needle disposal at home, and is test marketing in drugstores in Chicago soon. Fisher Scientific has tested it in Pittsburgh hospital test areas and found it useful and will probably market it this Fall.

South Carolina Police enjoy it use, as do a majority of major American Ambulance Companies, especially Southfield Fire Dept.

The NOPEK Oil Company has elected to establish world-wide manufacturing sites for all 4 products, the single, single OR, triple and wall box in February of 1992.

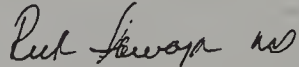
Many Visiting Nurse Associations and Hospice-Health Depta use it extensively.

It has FDA permission to sell and USA patent and Patents pending in Canada and multiple overseas countries.

Current Sales see following pages.

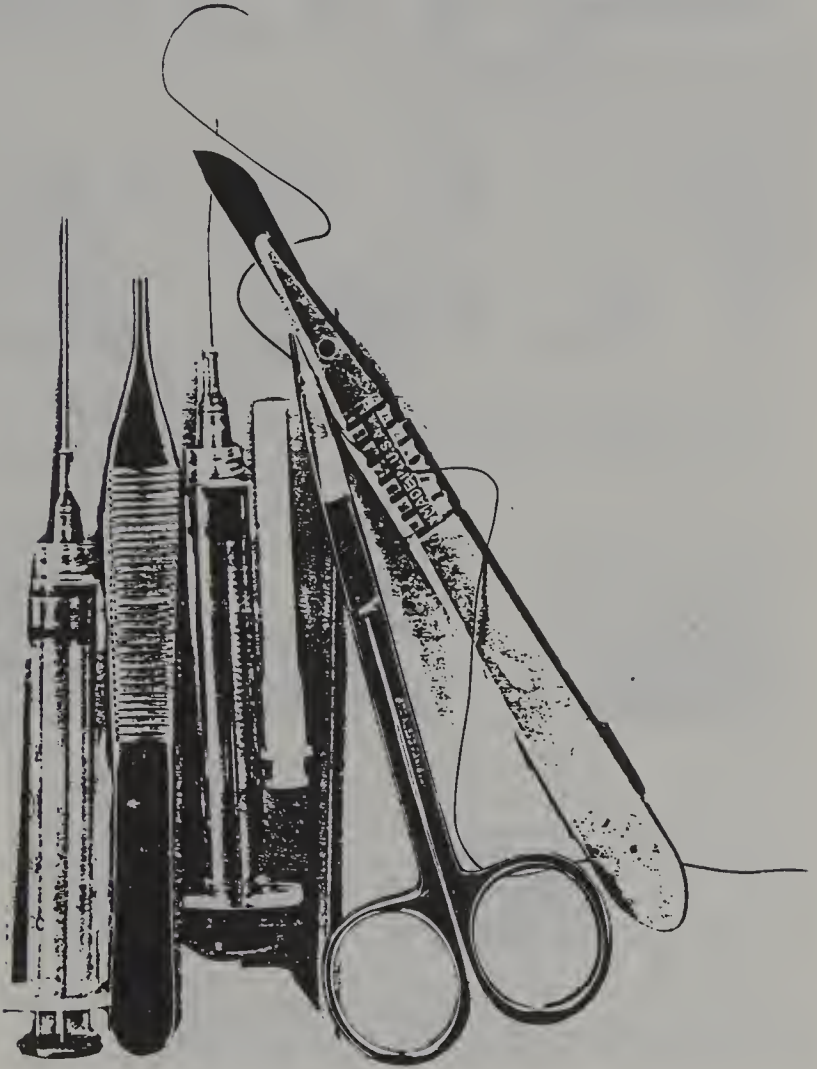
Financial Requirements and projections see following ppa.

Respectfully,



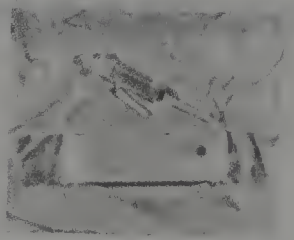
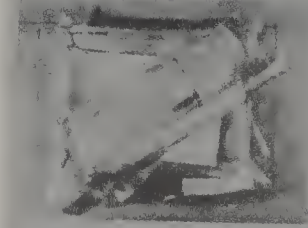
Rick Sawaya MD

Your Sharp Trap will hold all the instruments
seen below and more, even a subclavian set.

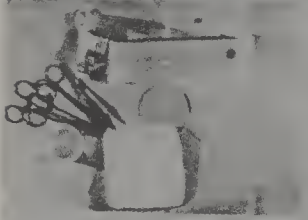


INSTRUCTIONS

SHARP-TRAP BIO-DISPOSABLE CONTAINER



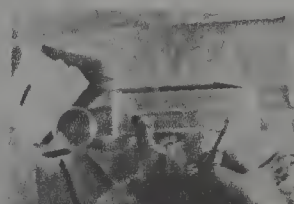
AFTER INSERTING THE DISPOSABLE SUTURE SET COMPLETELY, DISCARD IT TO LEAVE ROOM ON THE TRAY. THERE IS NO NEED TO PLACE ANY OBJECTS BACK ON THE TRAY. THE SHARP SAFE BOX IS STERILE AND CAN BE PLACED ON THE TRAY. AS SOON AS ANY INSTRUMENT IS USED, IT SHOULD BE IMMEDIATELY PLACED IN THE SHARP SAFE BOX. BE SURE TO PLACE THE SYRINGE FOR LOCAL IN THE BOX. IF MORE LOCAL IS NEEDED LATER, ONE CAN ASK FOR ANOTHER SYRINGE.



ITEM 1 - SYRINGES:

A. 10 CC. SYRINGES ARE HANDLED A LITTLE DIFFERENTLY BECAUSE OF THEIR SIZE. HANDLE THE BUTT END IN THE LEFT HAND AND ADVANCE NEEDLE POINT IN THE RIGHT HAND UNDER THE EDGE. KEEP THE RIGHT INDEX FINGER ABOVE THE DISTAL END OF THE SYRINGE AND DEPRESS THE BUTT END IN THE LEFT HAND. IT WILL FALL INTO PLACE EASILY. DO NOT LET GO OF THE SYRINGE FOR ANY REASON WHILE DEPRESSING. KEEP A FIRM HOLD, ESPECIALLY ON THE BUTT END.

B. SMALLER SYRINGES, 5, 3, 1 CC., TB, OR DIABETIC SYRINGES: BUTT IS HELD IN THE LEFT HAND AND NEEDLE IS ADVANCED RIGHT-HANDED OR RIGHT AND LEFT-HANDED INTO, UNDER THE EDGE OF THE DOOR. THEN, PRESSING THE ORANGE DOT WITH THE LEFT INDEX FINGER, THE SYRINGE WILL FALL IN. AGAIN, RIGHT INDEX FINGER IS GENTLY KEPT OVER THE DISTAL END OF THE SYRINGE. ABOUT THE 2 CC. MARK AND WHILE PRESSING ON THE ORANGE DOT, THE SYRINGE WILL FALL IN. IF FOR ANY REASON, THE 10 CC., 3 OR 5 CC. SYRINGES HANG UP OR DO NOT QUITE FIT IN, KEEP THE RIGHT INDEX OR TWO FINGERS OVER THE TOP, GENTLY PRESS, AND SHAKE THE BOX GENTLY AND IT WILL FALL INTO PLACE.



ITEM 2 - SUTURE HOLDERS: UPON COMPLETING REMOVAL OF SET, IMMEDIATELY PLACE HOLDER UNDER THE EDGE OF TRAY DOOR. RELEASE NEEDLE AND DRUP IN PLACE. THE TILT OF THE DOOR WILL KEEP THE HOLDER FROM PHILLING BACK OUT IF IT PHALLS IN FAR ENOUGH. REMOVE THE HOLDER HOLDER AND CONTINUE WITH NEXT STEP ESSENTIALLY. INSERTION OF THE SYRINGES, NEEDLES, NEEDLES, SCISSORS AND ASK FOR ANY SIMPLE HAND OVERS. 10 CC. SYRINGE IS ABOUT THE MAXIMUM THE BOX IS DESIGNED TO TAKE IN TERMS OF LENGTH AND SIZE. IT WILL HOLD ABOUT 20 CC. SYRINGES AS A RULE.

SHARP-TRAP® INC.

15777 West Ten Mile
Suite 200
Southfield, Michigan 48075
U.S.A.

1-313-552-1190
Fax 1-313-552-0332

January 30th '92.

Administrator
Hospital and Insurance Carrier:

Dear Sir:

You are not aware of the cost annually of a puncture wound.

You cannot assume that someone does not have AIDS or Hepatitis.

You will pay \$ 670.68 per patient or employee injury.

You will pay, non-insured possibly, \$ 80,481.60, per year for 10 puncture wounds a month.

You will pay, \$ 160,960.32 per year for 20 puncture wounds per month.

You will pay \$ 241,444.80 per year for 30 puncture wounds/month.

You cannot avoid the AIDS test on any employee or patient, injured and you cannot avoid testing the origin of the injury person. **

TEST	COST	NUMBER REQUIRED/YR	TOTAL COST	PW/Mos #No.	COST/ Yr.
AIDS	\$ 150/	3	\$ 450	10	\$ 54,000.c
HEPATITIS B AUSTRALIAN ANTIGEN PROFILES	\$ 103.59	2	\$ 207.18	10	\$ 2071.80
GAMMA GLOBULIN TETANUS TOXOID	\$ 5.00-(\$10) \$ 1.00 \$ 6.00 (\$16)	1	\$ 6.00	10	\$ 60.00
TIME OFF FLOOR TO ER OR HEALTH SERVICE 1/2 hr Minimum.				10 (5hrs)	

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1-313-552-1190
Fax 1-313-552-0332

January 30th *92.

TEST	COST	NUMBER REQUIRED/YR	TOTAL COST	No. of PW/Mos	COST/ Yr
AVERAGE	\$ 15.00/hr	(HRS OFF 5/10pts)	\$ 7.50	10	\$ 75.00
MINIMAL PAY					
Time off 1st and second visit here is only one visit considered.					

EMERGENCY
ROOM AND
HEALTH
SERVICE \$ 25.00/pt

This is usually professional courtesy.*

SINGLE INJURY \$ 670.68/pt
TOTAL COST:

TEN - 10 / Mos \$ 6706.68 x 12 = \$ 80,481.60

TWENTY- 20 / Mos \$ 13413.34 x 12 \$160,960.32

THIRTY 30 / Mos \$20,120.4 x 12 = \$241,444.80

Your responsibility morally and medical legally is to test every puncture wound as a POTENTIAL AIDS CASE.

The cost for the care of one AIDS patient is \$ 200,000. Tax dollars/yr.

Someone estimated that there were 800,000 puncture wounds last year

The cost of really checking 800,000 puncture wounds is \$5.3_____.

The cost of one AIDS puncture wound at Kings County Hospital NY = \$175,000,000.

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U.S.A.

1-313-552-1190
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January 30th 1992.

If your Hospital or institution gets 10 puncture wounds/mos,
you are spending about \$ 80,481.00 per year.

You are risking 10 lawsuits per month in not using
* the ONLY sharps container in the world which will
hold surgery suture instruments and subclavian sets.

* It is senseless for your nurse or doctor to leave instruments
on a tray for himself or a nurse to dispose of. And there
is no wall box which allows dumping of a CVP tray or Minor Suture
tray.

For the \$ 80,481.00 spent in one year for medical-legal costs,
you could eliminate puncture wounds completely and
purchase #40,000 Sharp-Trap devices Sterile type for ICU,CCU,ER
and NICU and PSYCHIATRY and never be sued,

You and your institution or hospital can someday be given and
insurance break, like the air-bag, for using the Sharp-Trap.

WE are trying to get your Insurance Carrier to drop your rates
if you use the Sharp-Trap System.

If your ER Census is # 20,000/ yr or better, you will
ERRADICATE minor suture injuries, save your nurses hand picking
an AIDS patients needles.

Consider the Sharp-TRap as your " bus boy" life insurance.

Please call us at 1-313-552-1190.

Respectfully,

Rick Sawaya M.D.
Rick Sawaya M.D.

Tuesday,
January 2,
1990 ••

Suit by doctor dying of AIDS seen as test

By Kelley Armstrong
Associated Press

NEW YORK — Veronica Prego had everything to look forward to at the age of 25 as she embarked on a medical career. Then she pricked her finger with an AIDS-contaminated needle and her world came crashing down.

Seven years later, Prego's \$175-million negligence lawsuit goes to trial today, while she fights to survive the ravages of AIDS.

Prego's lawyer, Diane Wilner, says Prego sued Kings County Hospital, its parent agency, the city and two doctors to ensure that other doctors are protected. It's her No. 1 priority — at least on the days that she's not being rushed to an emergency room with AIDS-related malady.

"She will die from it — that's a fact," Wilner said. "The only ques-

Please see AIDS/5A

The Detroit News

Nation&World

gouze and bed linens in which Fogel had "negligently and improperly" left a bloody needle.

WILNER SAID Prego reported her injury because the needle had been used to draw blood from a known AIDS patient.

"The powers that be assured her there were no reports of a health care worker getting AIDS through occupational exposure. At that time, that may very well have been a true statement," Wilner said.

Prego argues that the hospital failed to provide puncture-resistant containers for contaminated needles.

Fred Winters, a spokesman for the Health and Hospitals Corp., which operates city hospitals, says HHC hospitals were "in the forefront of following the known precautions" against AIDS transmission at the time. In addition, Kings County Hospital maintains that Fogel wasn't present when the blood was drawn and did not cause the injury.

PREGO TESTED positive for exposure to the AIDS virus in 1985 when she agreed to take part in a study on the incidence of the virus among health-care workers.

Prego says the researcher, Dr. Sheldon Landman of the State University of New York, told hospital personnel she was infected, even though she had been promised the results were confidential. He has denied any breach of confidentiality, but she has sued him as well.



ASSOCIATED PRESS

Dr. Veronica Prego: Life changed by an AIDS-contaminated needle.

In November 1987, Prego was diagnosed as having AIDS. She completed a fellowship from home and now works on research when her health permits.

Prego has said she fears the city "wants me to die" before trial can start. Hospital officials vehemently deny that.

"We have taken every step we can to expedite Dr. Prego's case so that she will have an opportunity to pursue her claim," Winters said.

SHARP-TRAP® INC.

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Suite 200
Southfield, Michigan 48075
U.S.A.

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Fax 1-313-552-0332

Dr. Thomas Arrowsmith-Lowe
F.D.A. Room 300
1390 Picard Drive
Rockville, MD 20850

Dr. Arrowsmith-Lowe,

I am writing to introduce you to a concept and a device that I developed which I feel is closely related to the focus of the upcoming Subcommittee hearing you will be attending February 7, 1992. I am confident that my device provides a viable solution to a very serious problem facing the medical community today — medical sharps containment, transport and disposal.

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The concept I envision is really quite simple. I suggest that the sharp medical instruments be deposited, by the user, directly in an escape-proof device during, or after use. This practice could eliminate secondary handling of contaminated sharps. This would serve to greatly reduce the occurrence of millions of puncture wounds being sustained by medical professionals in the U.S.A. every year. In addition to the need for a solution among medical professionals, we also have millions of diabetics who lack a standardized method for needle disposal. The SHARP-TRAP can fill this void. While providing safety and convenience to the users of medical sharps, this device would also protect those with the responsibility of transporting these contaminated instruments to landfills and incinerators.

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I would like to see major liability insurance carriers encourage the use of sharps containment systems by reducing premiums for conscientious users. I would also like to see major medical insurance carriers encourage use by diabetics by covering the device as a prescription item. Furthermore, in light of the seemingly uncontrollable proliferation of AIDS, I would like to see comprehensive government regulations regarding the handling and disposal of contaminated medical sharps.

Please take my thoughts and recommendations into consideration when you attend the hearing on February 7. Thank you.

Respectfully,

Rick Saucier MD

Rick Saucier MD

* The CDC recently told me that a recycling aluminum can factory was having a problem with too many needles and syringes in the cans, to recycle them.



SHARP TRAP INC.

FOR IMMEDIATE RELEASE

For Further Information

Contact:

Rick Sawaya, M.D.
President
Sharp Trap, Inc.
15777 West 10 Mile
Suite 200
Southfield, MI 48075
(313) 552-1190

NEW UNIQUE PATENTED SHARPS
BIO-DISPOSABLE CONTAINERS

In an era where the medical climate is one of increasing dangers of accidental exposure to transmittable diseases, it is comforting to know there is a new product that is a simple, yet ingenious, low-cost method of sharps disposal.

Sharp Trap can handle all types of sharps instruments including: syringes and needles, suture needles, blades, scissors and more. Once inside the Sharp-Trap, sharps instruments are out of harm's way and the unique patented design prevents them from accidentally falling out.

Sharp-Trap was invented by Dr. Rick Sawaya as a result of general surgery training and extensive emergency room experience with aids and related patients. This bio-disposable container is practical in all types of medical settings including: doctor's offices, clinics and a variety of hospital settings such as E.R., O.R., I.C.U., and N.I.C.U., visiting nurses and in-home use such as for diabetics.

The product is currently being used by hospitals, hospices, visiting nurses, police departments, ambulances, EMS units and others.]

Sharp-Trap is currently available in a single box, double box, triple box and an O.R. box. Other units are in prototype stages.

52-372 479

SHARP-TRAP® INC.

15777 West Ten Mile
Suite 200
Southfield, Michigan 48075
U.S.A.

1-313-552-1190
Fax 1-313-552-0332

Oct. 4, 1991.

Enclosed is a description of the only self-closing sterile and non-sterile sharp's container in the world. With its self-closing, overlapping doors, the box has successfully passed space-flights in zero-gravity testing cvp lines, arterial punctures, mouse surgery, needle counters etc.

It is a handy ashtray system which eliminates the need for transporting the needles, and puts the responsibility in the hands of the skilled physician

It is transparent, light-weight and capable of holding entire instrument trays, CVP's, Minor Suture Sets etc.

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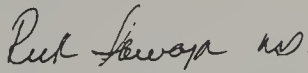
Many Visiting Nurse Associations and Hospice-Health Depts use it extensively.

It has FDA permission to sell and USA patent and Patents pending in Canada and multiple overseas countries.

Current Sales see following pages.

Financial Requirements and projections see following pps.

Respectfully,



Rick Sawaya MD



PROVIDENCE HOSPITAL

16001 WEST NINE MILE ROAD
P.O. BOX 2043
SOUTHFIELD, MICHIGAN 48037
313 424-3000

May 31, 1991

To Whom It May Concern,

As a health care professional it is of utmost importance to me to provide a safe environment for myself and my staff. Needle sticks and puncture wounds by sharp objects are a constant menace to the health care industry and a crucial concern in hospitals.

The sharp trap needle disposable box has been a real asset to my unit. Bedside sharp traps make disposing of sharps very easy and the sterile ones are ideal for sterile procedures done at the bedside. If the person performing a procedure can dispose of their sharps immediately it eliminates the risk of a second person being stuck.

Although, my usage is limited in the NICU I see this as most beneficial in all areas of hospital, outpatient, clinic and home care.

Yours Truly,

Linda S. Omstead RNC, CNM

Linda S. Omstead RNC, BSN
Clinical Nurse Mgr.
NICU/SCN/A.N.



NASA

MAN-SYSTEMS DIVISION

5/13/91

Rick:

Received the third generation Sharp Trap containers. Will use on upcoming flights.

Enclosed is evaluation of second generation issue from KC-135 zero-gravity flight.

Thanks.

Roger Billica MD
NASA JSC SD2

Evaluation of the Sharp-Trap Bio-Disposable Container

In general the Sharp-Trap container worked well, but there were some problematical areas. General comments are below.

The second prototype container was easier to open than the first because the lower flexible opening gate was more pliable than in the previous version. This represented a great improvement over the first prototype. I'm not sure if there was an intentional change in design to make the gate more flexible, or if the change was just subsequent to quality control variability. In any case, a more pliable lower gate is much easier to use.

Objects inside the container stayed there once placed inside. The container was thrown around, spun, and shaken and none of the contents showed even any little bit of escaping. Also the fluids inside were not released into the environment, but fluid release is a potential problem since biological waste almost always accompanies sharp waste (eg. used syringes, needles, scalpels, etc.). An inner lining may be a solution to this problem???

Floating of sharps inside the container did not seem to be a problem, although theoretically disposed sharps could float to the top and stick someone while s/he disposes of a sharp. A one way valve or gate may be an answer??? Use "stick 'em" inside???

The length of the container is not long enough to accommodate a larger size syringe with a long needle catheter, as was used in the CVP sim.

07/31/91

16:25

MATRX MEDICAL INC.

001



Dr. Richard Sawaya
President
Sharp Trap Inc.
15777 W. Ten Mile Road
Southfield, MI 48075

July 31, 1991

Dear Rick,

This letter is in reference to your Sharp Trap™ Blo-Disposable Container featured on page 55 of our 1991 Emergency Care Products Catalog. I must tell you that we are most surprised by the early sales results of this product. Since its introduction, we have seen a steady growth of this products sales. We are now currently selling about 400 per month.

As a major manufacturer and distributor of Emergency Care products worldwide its always nice to be able to include a product such as yours that will practically sell itself. Thank you for allowing us to include your invention in our product line. We hope there will be some additional innovative ideas produced by your company in the near future.

Sincerely,

A handwritten signature in dark ink, appearing to read "R. Bilger", is written over a horizontal line.

Richard Bilger
Marketing/Communications Manager

P.S. Our deadline for inclusion in our 1992 catalog is approaching fast. Please inform me as soon as possible if you have any additional products or any pricing or specification changes to your existing Sharp Trap.™

Tarr
 EMERGENCY PRODUCT SALES, INC.
 6106 BAUSCH ROAD, GALLOWAY, OHIO 43119
 614-878-8581 800-282-7904 FAX 614-878-3779

April 26, 1991

Rick Sawaya, MD
 SHARP-TRAP®
 15777 West Ten Mile
 Suite 200
 Southfield, MI 48075

Dear Rick,

Just wanted to let you know how much we appreciate the opportunity to work with you and the SHARP-TRAP®. It is a very unique product. We have been promoting and displaying the product for well over a year now and have many customers who currently use the SHARP-TRAP® on a daily basis. These customers include hospitals, nursing homes, individual diabetics, fire departments, Emergency Medical Service organizations, industrial accounts and police departments.

If you find anyone who needs a reference do not hesitate to give us a call, as we would have many such accounts.

Sincere Thanks,

Connie S. Lewis

Connie S. Lewis
 Sales Manager

PARAMED INC. 480 South Updyke, Pontiac, Michigan 48341

April 24, 1991

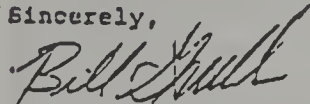
Dear Medical Professional,

I have been using the "Sharps Trap" sharps disposal system for one year in our Emergency Medical Service. I find the Sharps Trap very convenient in that the Paramedic is able to properly dispose of a needle or stylet directly after use in the patient's home.

Without the Sharps Trap, the Paramedic had a tendency to recap the dirty needle, exposing them to unnecessary risk. I don't know what we did before utilizing the Sharps Trap.

If you have any questions, feel free to call me at 313-456-0030.

Sincerely,



Bill Grubb
Quality Improvement Coordinator



DISTRIBUTOR PRICE LIST

Effective 5/1/91



15777 West Ten Mile
 Southfield, Michigan 48075
 Phone: (313) 552-1190
 Fax: (313) 552-0332

	CASES 50u/Case	1-4	5-9	10-99	100+
NON-STERILE SUGGESTED RETAIL \$1.59 EACH	per unit	\$1.30	\$1.25	\$1.20	\$0.95
STERILE SUGGESTED RETAIL \$1.99 EACH	per unit	\$1.70	\$1.65	\$1.60	\$1.35

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SHARP-TRAP® INC.

Rick Sawaya, M.D.
1-313-552-1190
Fax 1-313-552-0332

15777 West Ten Mile
Suite 200
Southfield, Michigan 48075
U.S.A.





COUNTY OF ORLEANS
DEPARTMENT OF HEALTH

ANDREW LUCYSZYN, MPA
Public Health Director

14012 Route 31
Albion, New York 14111
(716) 589-7004
FAX (716) 589-6647

MARILYN POWLEY, BSN
Director of Patient Services

January 6, 1992

Dr. Rick Sawaya
SHARP-TRAP INCORPORATED
15777 West Ten Mile Road
Suite 200
Southfield, Michigan 48075

Dr. Sawaya,

Our Home Health Agency nurses make home visits to patients who occasionally need injections of medications. The Sharp-Trap has been particularly useful in situations in which a single needle and syringe is used and then needs to be disposed of immediately.

Most sharps containers are too large or bulky for transporting from office to patient's home and back. The Sharp-Trap is conveniently shaped to be carried easily in the nurse's bag. The used syringe and needle can be disposed of into the Sharp-Trap quickly and safely without risk of needle-stick accidents and then brought back to the office.

Sincerely,

Marilyn Powley

Marilyn Powley
Director of Patient Services

MP/bk

The logo for Westland Medical Center features a large, stylized 'W' on the left, followed by the word 'ESTLAND' in a bold, sans-serif font. To the right of 'ESTLAND' is a stylized 'M' that incorporates a large, curved 'C' shape, followed by the word 'EDICAL' in a bold, sans-serif font, and finally the word 'ENTER' in a bold, sans-serif font on the far right.

WESTLAND MEDICAL CENTER

2345 Merriman Road

Westland, Michigan 48185

(313) 467-2300

March 14, 1990

To Whom It May Concern:

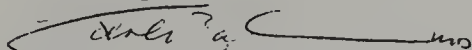
I have reviewed the disposable sharps container designed by Dr. Sawaya in reference to possible utilization of the container in prepacked surgical suture sets.

With the heightened awareness in the medical community in regard to the potential of transmitting the AIDS virus from contaminated needles, the safe disposal of syringes and needles have become high priority both in the operating room and emergency room setting.

The idea of a sterilypacked small container in the operating field for the disposal of needles and syringes immediately after they are used is therefore a very attractive concept.

It is my opinion that this container, if routinely included in prepacked surgical kits, could significantly contribute to increase the safety of surgical procedures.

Sincerely,

A handwritten signature in dark ink, appearing to read 'Karl O. Bandlien', is written over a horizontal line.

Karl O. Bandlien, M.D.
Chairman, Department of Surgery
Westland Medical Center

met



Department of Police
Detroit, Michigan 48226

Coleman A. Young, Mayor
City of Detroit

August 15, 1990

Doctor Rick Sawaya
Sharp-Trap Inc.
15777 W. Ten Mile Road
Southfield, Michigan 48075

Dear Doctor Sawaya:

I have reviewed the bio-disposable container dubbed the "Sharp Trap" in reference to its possible utilization by the Detroit Police Department's Narcotics Division.

In considering the ever increasing number of persons contracting the Aids Virus, your device appears to quite readily meet the needs of protection against possible contamination from syringes at the storage stage of the process.

It is the opinion of this writer that though safe disposal of narcotic paraphernalia is crucial after confiscation, it is this Department's interest to obtain a device which will allow an officer, when conducting the initial search and seizure, to avoid being accidentally pricked by a contaminated needle.

Therefore, the Detroit Police Department's Narcotics Division supports the use of the "Sharp Trap" in an effort to reduce contamination, but respectfully declines its employ at this time.

Sincerely,

GEORGE M. ROSSER
Sergeant
Detroit Police Department
Narcotics Division

GMR:sf

TO WHOM IT MAY CONCERN:

Enclosed find material on a fascinating and enjoyable new PORTABLE way to deal with you "SHARPS" problem, both sterile and non-sterile.

Designed by a Detroit Medical Doctor, the SHARP-TRAP is a well received device by many Administrators, Emergency Room Physicians, Nurses and Paramedics.

Some of their comments are enclosed for you.

The SHARP-TRAP is excellent for IV's and IM injections on the floors and at the bedside, it is also transparent.

Your device will be shipped to you either sterile, for use in the emergency room and operating room or it will be shipped non-sterile for other random procedures.

The SHARP-TRAP device will help eliminate your nurses from cleaning up after suturing and doctors. It will also help keep your establishment happier, more secure and litigation free.

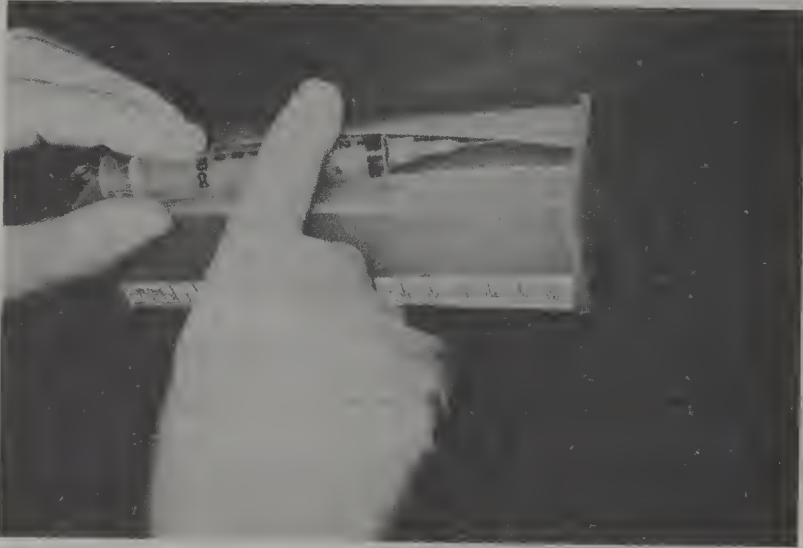
Respectfully,

Frederick J. Sawaya M.D.

Frederick J. Sawaya, M.D.

SHARP-TRAP

BIO-DISPOSABLE CONTAINER



The purpose of the disposable needle holder, is to prevent injury to nurses and physicians and paramedical personnel on needles on the operating room table, or suture table in the emergency room, or clinic or office setting, and to prevent injury to ambulance and paramedical people in the field.

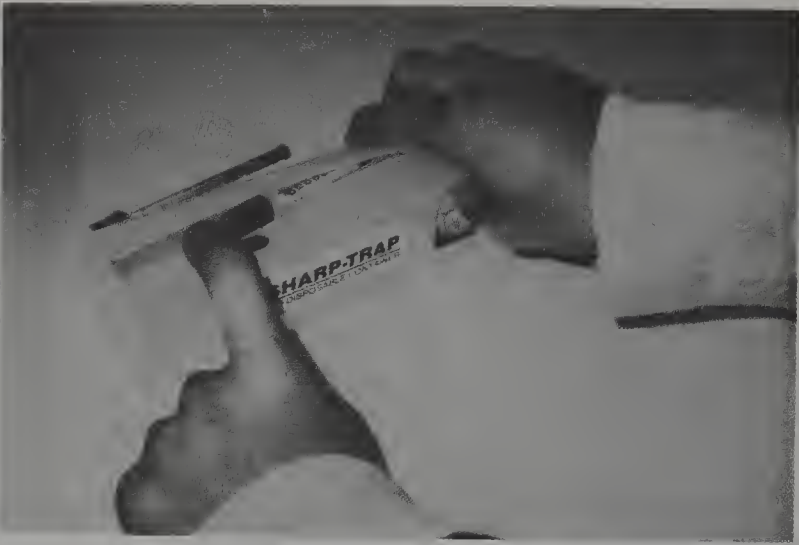
Try to insert all the points to the right, with your right index finger curved gently over the sharps handle on the right and your left index finger depressing the object inward, or most simply pressing on the orange dot.

When you are finished and all sharps, scissors, blades and suture needles are all inside the box, attach the biohazard label across the doors, and insert the box into the polybag along with closed hemostats and sponges or paper waste, leaving the help a fairly clean and very safe field to clean.

SHARP-TRAP, INC.
 15777 West Ten Mile Road
 Suite 200
 Southfield, Michigan 48075 U.S.A.
 Phone: (313) 552-1192
 Fax: (313) 552-0332
 U.S. Patent

**Thank You
 for Your Order**





The diabetic at home no longer needs
a coffee can for his or her needles.

You may dispose of the entire syringe or the end-broken off,
by inserting them into the box.

The box is very durable, it will not puncture or break,
apply a rubber band when full. The Sharp-Trap holds about a
dozen insulin syringes and is conveniently small enough to
take on a trip, vacation or visiting.

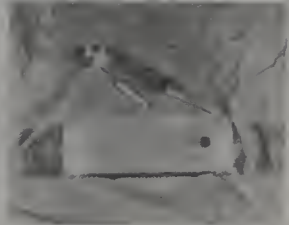
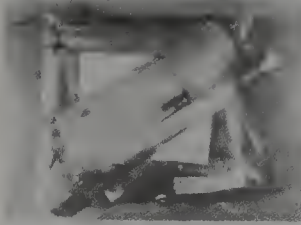
Your Sharp-Trap is safe, simple and tidy.

U.S. Patent

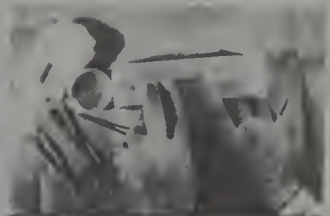




INSTRUCTIONS

SHARP-TRAP
BIO-DISPOSABLE CONTAINER

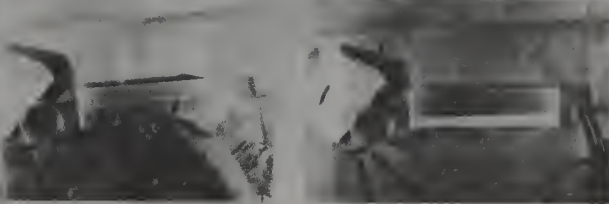
AFTER EMPTYING THE DISPOSABLE SYRINGE SET COMPLETELY, DISCARD IT TO LEAVE ROOM ON THE TRAY. THERE IS NO NEED TO PLACE ANY OBJECTS BACK ON THE TRAY. THE SHARP-SAFE BOX IS STERILE AND CAN BE PLACED ON THE TRAY, AS SOON AS ANY INSTRUMENT IS USED, IT SHOULD BE IMMEDIATELY PLACED IN THE SHARP-SAFE BOX. WE SUGGEST PLACING THE SYRINGE FOR LOCAL IN THE BOX. IF MORE LOCAL IS NEEDED LATER, ONE CAN ASK FOR ANOTHER SYRINGE.



ITEM 1 - SYRINGES:

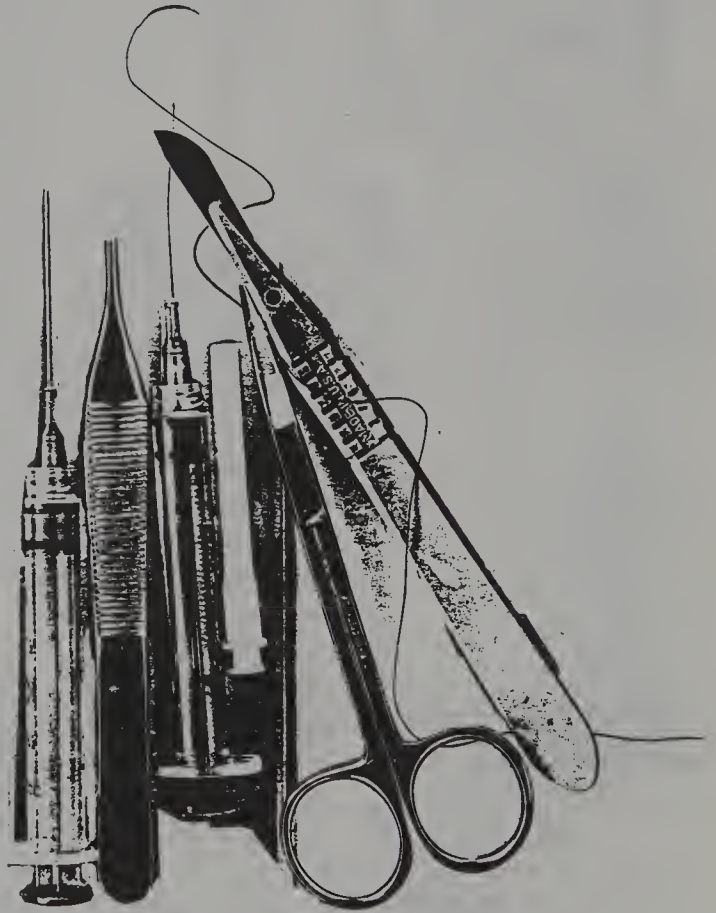
A. 10 CC. SYRINGES ARE HANDLED A LITTLE DIFFERENTLY BECAUSE OF THEIR SIZE. HANDLE THE BUTT END IN THE LEFT HAND AND ADVANCE NEEDLE POINT IN THE RIGHT HAND UNDER THE EDGE. KEEP THE RIGHT INDEX FINGER ABOVE THE DISTAL END OF THE SYRINGE AND DEPRESS THE BUTT END IN THE LEFT HAND. IT WILL FALL INTO PLACE EASILY. DO NOT LET GO OF THE SYRINGE FOR ANY REASON WHILE IMPRESSING. KEEP A FIRM HOLD, ESPECIALLY ON THE BUTT END.

B. SMALLER SYRINGES, 5, 2, 1 CC., 10, OR DIAMETRIC SYRINGES: BUTT IS HELD IN THE LEFT HAND AND NEEDLE IS ADVANCED RIGHT-HANDED OR RIGHT AND LEFT-HANDED INTO, UNDER THE EDGE OF THE DOOR. THEN, PRESSING THE ORANGE DOT WITH THE LEFT INDEX FINGER, THE SYRINGE WILL FALL IN. AGAIN, RIGHT INDEX FINGER IS GENTLY KEPT OVER THE DISTAL END OF THE SYRINGE, ABOUT THE 2 CC. MARK AND WHILE PRESSING ON THE ORANGE DOT, THE SYRINGE WILL FALL IN. IF FOR ANY REASON, THE 10 CC., 3 OR 5 CC. SYRINGES HANG UP OR DO NOT QUITE FIT IN, KEEP THE RIGHT INDEX OR TWO FINGERS OVER THE TOP, GENTLY PRESS, AND SHAKE THE BOX GENTLY AND IT WILL FALL INTO PLACE.



ITEM 6 - SUTURE NEEDLES: UPON COMPLETING REMOVAL OF STITCH, IMMEDIATELY PLACE NEEDLE UNDER THE EDGE OF FLAP-DOOR, RELEASE NEEDLE AND DROP IN PLACE. THE FIT OF THE DOOR WILL KEEP THE NEEDLE FROM PULLING BACK OUT IF IT PLACED IN FAR ENOUGH. REMOVE THE NEEDLE HOLDER AND CONTINUE WITH NEXT STEP. ESSENTIALLY, INSIDE OF THE SYRINGES, NEEDLES, SCALPES, SCISSORS AND ADSON ARE ALL SIMPLE HANDLERS. 10 CC. SYRINGE IS ABOUT THE MAXIMUM THE BOX IS DESIGNED TO TAKE IN TERMS OF LENGTH AND SIZE. IT WILL NOT ADMIT 20 CC. SYRINGES AS A RULE.

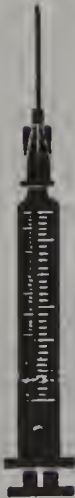
Your Sharp Trap will hold all the instruments
seen below and more, even a subclavian set.



This entire set can be disposed of using the Sharp-Trip which is exceedingly simple and handy.



ONE Ampule Lidocaine HCl 1%
USP 1% (10 mg/mL), 5 mL



ONE 3 cc Syringe with 25 G Needle



ONE 5 cc Syringe



ONE 5 cc Syringe with 22 G
Locating Needle



ONE Straight and
"J" Tip Guidewire



ONE Scalpel with No. 11 Blade



The Detroit News

Nation&World

Tuesday,
January 2,
1990 ••

Suit by doctor dying of AIDS seen as test

By Kiley Armstrong
Associated Press

NEW YORK — Veronica Prego had everything to look forward to at the age of 25 as she embarked on a medical career. Then she pricked her finger with an AIDS-contaminated needle and her world came crashing down.

Seven years later, Prego's \$175-million negligence lawsuit goes to trial today, while she fights to survive the ravages of AIDS.

Prego's lawyer, Diane Wilner, says Prego sued Kings County Hospital, its parent agency, the city and two doctors to ensure that other doctors are protected. It's her No. 1 priority — at least on the days that she's not being rushed to an emergency room with AIDS-related malady.

"She will die from it — that's a fact," Wilner said. "The only ques-

Please see **AIDS/5A**

AIDS

Dying doctor's suit is test case for her profession

From page 3A

tion is when."

The case is "terribly important" because it could set a precedent that hospitals are liable when an employee is infected, said Larry Gostin, associate professor of health law at the Harvard School of Public Health and executive director of the American Society of Law and Medicine.

EVEN BEFORE the trial, there has been sensationalism.

There have been charges the defendants' lawyers stalled so Prego would die before the case went to trial. The state attorney general's office subpoenaed her sympathy cards to ferret out sympathetic jurors.

In the end, it comes down to what a jury will believe happened in January 1983.

Prego was a medical school graduate working under a licensed physician in preparation for a hospital internship. She says she was cleaning up after an intern, Dr. Joyce Fogel, when she reached into a tangle of

gauze and bed linens in which Fogel had "negligently and improperly" left a bloody needle.

WILNER SAID Prego reported her injury because the needle had been used to draw blood from a known AIDS patient.

"The powers that be assured her there were no reports of a health care worker getting AIDS through occupational exposure. At that time, that may very well have been a true statement," Wilner said.

Prego argues that the hospital failed to provide puncture-resistant containers for contaminated needles.

Fred Winters, a spokesman for the Health and Hospitals Corp., which operates city hospitals, says HIIC hospitals were "in the forefront of following the known precautions" against AIDS transmission at the time. In addition, Kings County Hospital maintains that Fogel wasn't present when the blood was drawn and did not cause the injury.

PREGO TESTED positive for exposure to the AIDS virus in 1985 when she agreed to take part in a study on the incidence of the virus among health-care workers.

Prego says the researcher, Dr. Sheldon Landesman of the State University of New York, told hospital personnel she was infected, even though she had been promised the results were confidential. He has denied any breach of confidentiality, but she has sued him as well.



Dr. Veronica Prego: Life changed by an AIDS-contaminated needle.

In November 1987, Prego was diagnosed as having AIDS. She completed a fellowship from home and now works on research when her health permits.

Prego has said she fears the city "wants me to die" before trial can start. Hospital officials vehemently deny that.

"We have taken every step we can to expedite Dr. Prego's case so that she will have an opportunity to pursue her claim," Winters said.

S H A R P T R A P

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Paramed Suburban Ambulance Fleet	NS	40 Boxes @ \$1.30 ea.	6/90	\$ 52.00	NC	\$ 52.00
Parr Emergency Services	NS	200 Boxes @ \$.70 ea.	8/90	\$140.00	YES	\$140.00
Paramed-Suburban Fleet	NS	140 Boxes @ \$1.25 ea.	8/90	\$ 50.00	NC	\$ 50.00
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NICU	NS	50 Boxes @ \$1.25 ea.	8/90	\$ 62.50	YES	\$ 62.50
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		Invoice No: 9264				

Grady Memorial Hospital
Oct. 10, 1990: Approved for purchase and use in diabetic section
C/O Ron Schinault

Med-Trap Inc. Distributor to New York State Hospitals
New York, New York
(212) 628-1343 Mr. Munoz and Mr. Thaler

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NON-STERILE <i>SUGGESTED RETAIL \$1.59 EACH</i>	per unit	\$1.30	\$1.25	\$1.20	\$0.95
STERILE <i>SUGGESTED RETAIL \$1.99 EACH</i>	per unit	\$1.70	\$1.65	\$1.60	\$1.35

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SHARP-TRAP®

BIO-DISPOSABLE CONTAINER

Designed by a Michigan doctor, SHARP-TRAP® offers a safe, practical and cost effective method of disposing of syringes, sutures, and other potentially dangerous sharp instruments in either a sterile or non-sterile environment.



For CVP and Laceration Trays

Use the single non-sterile SHARP-TRAP® container for bedside injections. No need to walk across the room with a contaminated needle



The "Sharps" Deposit Box

For more information on Sharp-Trap®, contact your local distributor or call 1-313-552-1190.



Sharp-Trap® Inc.
15777 W. 10 Mile Road
Suite 200
Southfield, Michigan 48075





THE NEW UNIQUE, PATENTED BIO-DISPOSABLE CONTAINERS

In an era where the medical climate is one of increasing dangers of accidental exposure to transmittable diseases, it is comforting to know there is a new product that is a simple, and low cost method of sharps disposal.

SHARP-TRAP®

Is being used in hospitals and emergency vehicles across the United States. Sharp-Trap® has been successfully tested in space at zero gravity.

SHARP-TRAP®

Helps prevent injury to nurses, physicians and paramedical personnel from sharp instruments in the operating room, emergency room, clinic and office settings. Sharp-Trap® is a necessity to ambulance and EMS personnel in the field.

SHARP-TRAP®

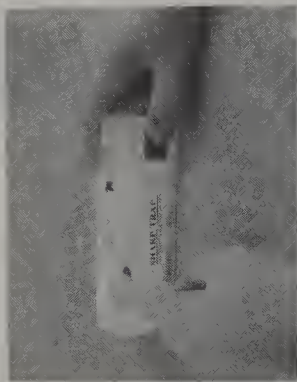
Can handle all types of sharp instruments including: syringes and needles, suture needles, blades, scissors and more. Once inside the Sharp-Trap®, sharp instruments are out of harm's way and the unique patented design prevents them from accidentally falling out.

Use the double sterile SHARP-TRAP® container complete with suture counter for those SPECIALTY PROCEDURES



Operating Room Counter

Each SHARP-TRAP® comes complete with a plastic bag and rubberband to allow for proper disposal of bio-hazardous items.



Emergency Room • Emergency Vehicles • ICU • Obstetrics • Diabetics

USING SHARP-TRAP® IS EASY.

- Place Sharp-Trap® box with the label facing you.
- Insert the sharp edge of the instrument under the top flap at the right (label) end of the box and place right index finger over the handle or barrel.
- Depress the orange dot with left index finger until the object drops into the box.
- Attach the rubber band around the box and insert into the polybag.
- Deposit in the most ecologically-efficient site available.

Sterimatic Safety Needle

Currently available as:

1.5" 21G (0.8 x 40mm) hypodermic needle to fit
all syringes



Code No: SSN 150 - 21
Cartons of 100

3" 21G (0.8 x 40mm) blood collection needle
to fit all evacuated blood collection
systems



Code No: SSNBC 150 - 21
Cartons of 100

Sterimatic Medical Systems Ltd.

Abnash, Chalford Hill, Stroud,
Gloucestershire, GL6 8QN, United Kingdom.
Tel: 0453 884944 Fax: 0453 886481

*Registered Trade Mark. World Patents Pending.

**If this needle
pricks you it could
give you Hep B or
even HIV**



THIS NEEDLE WON'T THE NEW Sterimatic Safety Needle

Any needle, once it has contacted untested blood, is a potentially lethal instrument. Accidental needlestick injuries are the main cause of occupationally acquired Hep B, HIV and other infections.

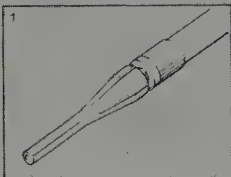
Such injuries occur, all too often, both during use and after disposal of needles. Needlesticks are the second most common injuries to staff in hospitals (after back strain) and certainly the most dangerous.

The spread of Hep B and HIV amongst the patient population has highlighted the serious implications of needlestick injury. Healthcare personnel, particularly those working in high risk areas (Haematology, Casualty, IC, STD, Renal, etc) need protection from potential infection and consequent anxiety. Hospital management need to reduce the cost of post-needlestick testing and potential liability.

Devices intended to make the manual resheathing of needles safer are no answer - they will not protect during needle use or against careless disposal. What is needed is a new safety needle that automatically and permanently covers the needle point as soon as it is withdrawn from the patient: an accident-proof needle.

The **STERIMATIC SAFETY NEEDLE (SSN)** is safer by design because once the point of the needle has been introduced into the patient, no part of the needle, including the point, is ever exposed.

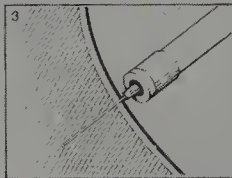
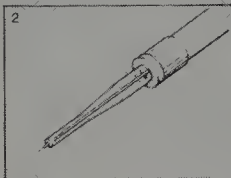
Sounds impossible? Here's how the SSN works:



1. The SSN is removed from a sterile pack and fitted to any syringe or evacuated blood collection system, like any ordinary needle.

2. The sheath is removed to reveal the needle point exposed beyond a transparent sleeve.

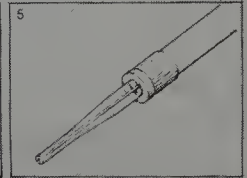
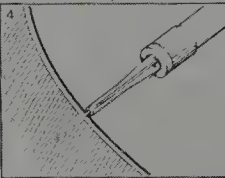
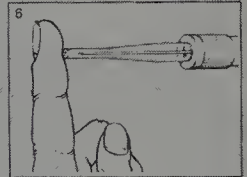
3. The needle point is introduced into the patient and the transparent sleeve retracts freely to allow the required penetration.



4. When the needle is withdrawn, the sleeve slides forward to cover the whole length of the blood contaminated needle.

5. As the needle is fully withdrawn, the sleeve automatically covers the needle point and locks permanently over it.

6. The needle is now rendered completely and permanently safe against needlestick.



The **STERIMATIC SAFETY NEEDLE** has been extensively trialled by the DoH and has proved its efficiency in providing the highest level of protection and safety. A copy of the DoH Trial Report is available free to healthcare personnel on request to Sterimatic Medical Systems Ltd.

ISBN 0-16-039065-6



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